



**KERRY**

Leading to Better

# Kerry Technical Seminar – Dubai

## July 8, 2019

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## Agenda

Time	Topic
8:30	Registration
9:00	Kerry – The Leading Taste and Nutrition Company
9:30	Increase your competitive advantage with our innovative SheffCoat™ - Aqueous Based Coating Systems
10:30	Q&A
10:45	Coffee Break
11:00	Improving Efficiency - Troubleshooting Coating and Case Study Discussion
12:00	Q&A
12:30	Lunch
14:00	Maximise the Effectiveness of your formulation with Kerry Excipients – 1
15:30	Coffee Break
16:00	Maximise the Effectiveness of your formulation with Kerry Excipients – 2
17:30	Q&A, Certificate Distribution

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## Kerry Global Credibility

Quoted on the London & Dublin Stock Exchanges



Corporate  
Headquarters  
Tralee, Ireland



25K+

Employees



900+

R&D Scientists



140+

Countries of Sales



147

Production Locations



15K

Products



27

Countries of Operation

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Delighting and nourishing consumers across the globe with products people enjoy and feel better about.

### Our Vision

To be the leader in taste and nutrition for the global food, beverage and pharmaceutical industries, creating sustainable value for our customers, employees, environment, community and shareholders.

### Our Mission

To help delight and nourish consumers across the globe.

### Our Values



Commitment



Excellence



Teamwork



Value Creation



Entrepreneurship

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## Our Unparalleled Go-To-Market Footprint

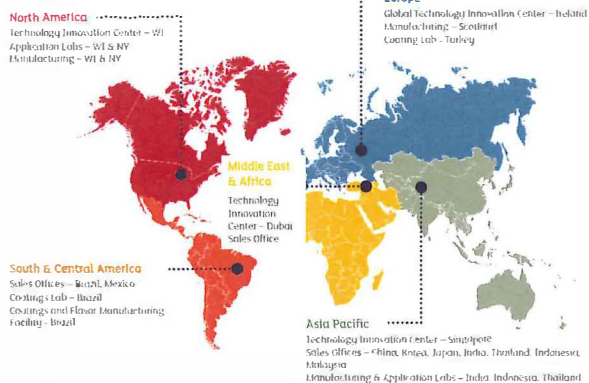
A global footprint with operations in 27 countries



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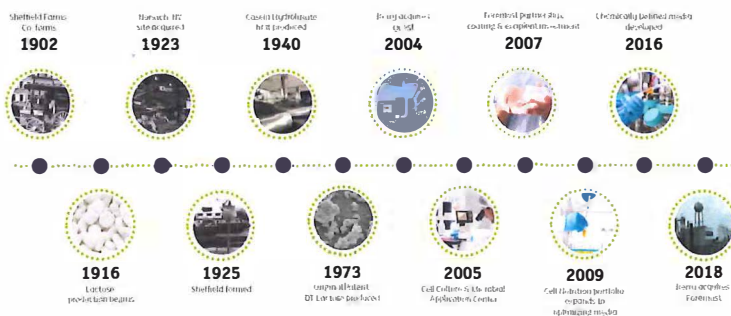
## Pharma's Global Presence



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## Over 75 Years of Strategic Pharma Evolution



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## Global Capabilities



### Supply Chain

- Global warehousing
- Validated dual manufacturing sites
- Supply agreements with multi-national pharma companies
- Traceability



### R&D

- In-house application labs
- Complete analytical and chemistry labs
- State of the art pilot plants
- Customer collaborations
- Extensive knowledge in scale-up from bench to production



### Manufacturing

- Over 75 years of experience
- CFR 210-11 registered and/or inspected facilities
- No 483's in history
- cGMP manufacturing
- Active IPEC member
- Compliant with all monographs and regulations
- Validated batch process



### QA & Regulatory

- Import/export documentation
- Questionnaires
- Customer audits
- Specification review
- Supplier documentation
- Global QA & regulatory teams
- Liaison with regulatory bodies
- Kosher compliant

## Excipients Manufacturing Facilities



Norwich, USA

- Entire Lactose Portfolio
- SheffCoat™



São Paulo, Brazil

- Coatings
- Flavors



Rothschild, USA

- Anhydrous DT and DTHV
- Spray Dried
- Crystalline Monohydrate
- Sheffield Inhalation grades
- Reddi Flo® AG



China

SheffCel™ (HPMC)



Vadodara, India

- Crystalline Monohydrate
- SheffCoat™



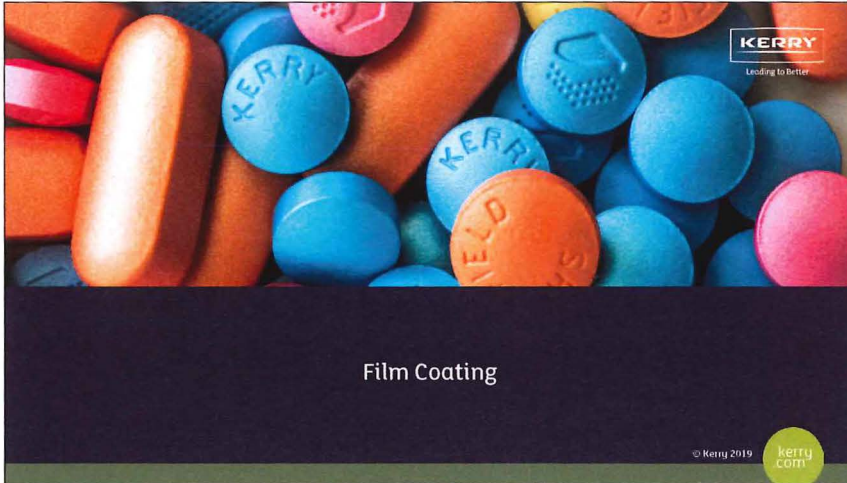
Flavors

Multiple facilities around the world including Italy, India, US

## Industry Trusts Kerry








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## Tablet Film Coating

Why coat tablets?

Aesthetics	Protective Function	Targeted Drug Delivery
<ul style="list-style-type: none"> <li>- To improve taste</li> <li>- To improve appearance and make tablets smoother/easier to swallow</li> <li>- Dose discrimination/safety considerations</li> </ul>	<ul style="list-style-type: none"> <li>• Protect core / API from moisture and oxygen</li> <li>• Protect core from chipping / erosion</li> </ul>	<ul style="list-style-type: none"> <li>- Sustained release coatings allow for release of API over time</li> <li>- Delayed release - Enteric coatings for targeted release at specific pH/area of digestive tract</li> <li>• Targeted drug delivery or protect API from stomach pH</li> </ul>

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## Ideally, Tablet Film Coatings...



- Protect the tablet during packaging, shipping, and storage
- Dissolve at the right time
- Have the right appearance (color, shine, texture)
- Let any underlying logos or embossing show through
- Are easy to apply
- Are a science, not an art

## The ideal film coating...

<b>disperses at high solids / applies rapidly</b> <ul style="list-style-type: none"> <li>• quickly protects cores</li> <li>• Process is efficient</li> </ul>	<b>offers moisture / oxygen barrier</b> <ul style="list-style-type: none"> <li>• API is more stable</li> <li>• More packaging options</li> </ul>
<b>Has low viscosity when dispersed</b> <ul style="list-style-type: none"> <li>• Resulting coating is smooth</li> <li>• Dispersion is easy to pump and spray</li> <li>• Less likely to foam or clog</li> </ul>	<b>has high opacity</b> <ul style="list-style-type: none"> <li>• Minimizes weight gain</li> <li>• tablets are uniform in appearance</li> <li>• Protects light sensitive APIs</li> </ul>
<b>is strong</b> <ul style="list-style-type: none"> <li>• physical protection for tablet</li> </ul>	<b>is smooth</b> <ul style="list-style-type: none"> <li>• Tablets are easy to swallow</li> <li>• Tablets easy to package</li> </ul>
<b>is elastic</b> <ul style="list-style-type: none"> <li>• logos are well defined</li> <li>• Film does not crack</li> </ul>	<b>has high adhesion</b> <ul style="list-style-type: none"> <li>• logos are well defined</li> <li>• Film does not peel from tablet easily</li> </ul>

## Immediate Release Film Coatings

- Designed to dissolve in the stomach, usually within a few minutes
- Immediate release are by far the most common types of tablet coatings
- A typical immediate release film coating is only 1-3% of the weight of the tablet...
  - 1% for clears, 2-3% for colored coatings





## Film Coating is Composed of Polymers and Plasticizers

## Polymers

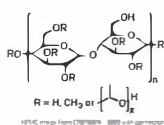
- Polymer gives the coating its **strength**
- Inter and Intra-molecular forces between polymer chains / side chains result in formation of a film, and determine the strength of a film
  - Intermolecular attractive force may involve dipole interactions
- Strength also results from intermolecular friction as a result of shearing forces. Higher strength can result in poor logo definition in some applications
- Films formed from polymers alone may be **brittle** and crack

HPMC, PVA, HPC, ethylcellulose are common polymers



## Hydroxypropyl Methyl Cellulose (HPMC)

- HPMC used in film coating is E-chemistry (USP type 2910)
  - Higher % substitution = more water soluble
  - available in different molecular weights/viscosities (i.e. E-6, E-15)
  - Higher viscosity = higher strength
- HPMC for extended release tablet cores is often K-chemistry (USP type 2208)
  - Lower % substitution = more tendency to create a less soluble gel – ideal for an extended release matrix



HPMC image from CPhI 2018

	E Chemistry	E Chemistry
% Methoxyl	29	22
% hydroxypropyl	8.5	8.1

\* Spray Sitagliptin on Metformin tablets

### PVA (polyvinyl alcohol)

- Used by pharmaceutical and nutritional supplement companies for > 10 years
- Low viscosity polymer – increases processing efficiency
- Produces a very strong, elastic coat with excellent adhesion
- Approved for use in nutritional supplements and pharmaceuticals in US and EU
  - Sprayed at higher temperatures (45 – 50C)
  - PVA cannot be sprayed with organic systems (insoluble!)

at 35°C for soft gel capsules.

### Performance of coating films improves with plasticizers

- Make the film more flexible / **elastic**
- Improving logo definition and decreasing cracking
- Minimum film forming temperature
- Plasticizers lower the glass transition temperature (T<sub>g</sub>)



### Plasticizer choice depends on several factors

- PEG / Macrogol. Commonly used
- Triacetin or triethyl citrate
- Propylene glycol
- Fractionated coconut oil
- Glycerin
- Acetylated monoglycerides





## Enteric Coating Polymers

- pH Dependent Release
- Polymer options:
  - Methylethacrylate Copolymers – most cost effective polymer / pH 5.5 release
  - HPMC Acetate Succinate – used for higher pH release.
  - HPMC Pthalate – used for very acid sensitive APIs



Acrylate copolymer  
CAP  
HPMC-P

## Colorants for Tablet Coatings



### Titanium Dioxide

Creates a white coating  
Acts as opacifier for other colored coatings  
Insoluble pigment



### Artificial Dyes & Lakes

In US, regulated and certified by the FDA (FD&C and D&G colorants)  
Lakes are insoluble  
Dyes are water soluble



### Iron Oxides

Red, yellow, and black  
Provide color & opacifying ability at the same time  
Insoluble pigment

## Pearlescent appearance with titanium / mica pigments

- Pearlescent pigments are composed of a mica substrate and titanium dioxide coating.
- They are gaining rapid acceptance in many countries as a colorant for foods and pharmaceuticals.
- Are often used to create a premium appearance



## Artificial Colors

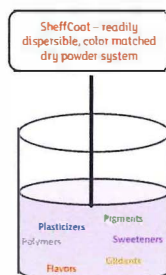
- The following are often used for nutritional supplements
  - FD&C Blue #1
  - FD&C Blue #2
  - FD&C Red #40
  - FD&C Yellow #5
  - FD&C Yellow #6
- Artificial colors were developed to provide a consistent, stable, and vibrant color for consumers.
- This defined consumer expectations of what a product should look like.

## Non-artificial Colors

- There is an increasing interest in removing artificial colors from products.
  - FD&C Yellow #5 – link to hyperactivity in US (requires a label for drugs in the US)
  - “Southampton Six” – azo dyes (red and yellow). A study in the UK linked these 6 colorants to hyperactivity.
- The FDA does not classify colorants as Natural or Synthetic, but there are a number of colorants that are “exempt from certification”. Many of these could be considered “natural”
- Since non-synthetic colorants are typically derived from natural sources, color variability and color stability are often a concern.

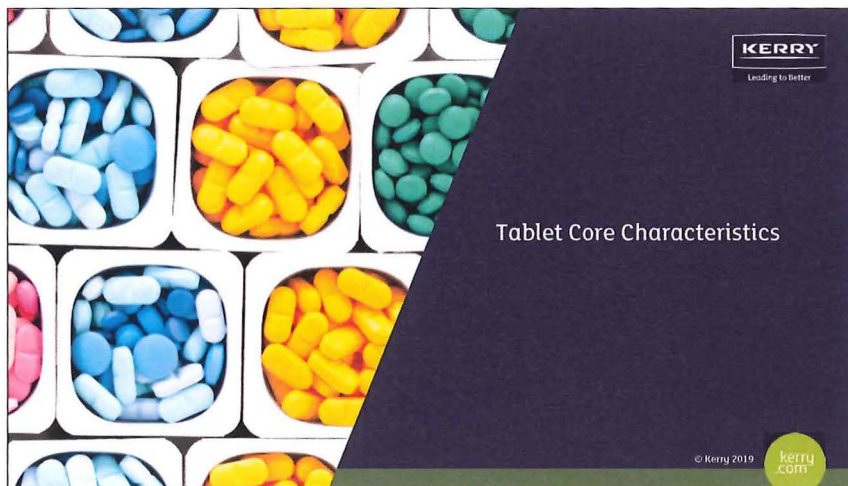
## Preparation of coating suspension with SheffCoat™

- Single component sourced, released, dispensed
- Solvent (water) is dispensed into tank
- SheffCoat added and stirred under low shear mixing to create a uniform mixture





Questions?



## Tablet Hardness is a Critical Parameter

- A minimum value of 8 kp is often used
- Limits vary with tablet shape and coating process
- Hardness is a factor of
  - compression force
  - tablet shape / size,
  - Formulation
  - Processing (blending time)
- Tablet to tablet variation can be improved by matching working lengths of tablet punches



## Tablet Friability is a Critical Parameter

- Measures % mass lost to dust and chips after 100 revolutions in 4 minutes
  - Friability less than 0.1% on uncoated cores is ideal
- Higher limits are possible with a good coating process
- Coated tablets may be "stress tested" to mimic effects of transport, handling.
  - Particularly useful for functional coatings

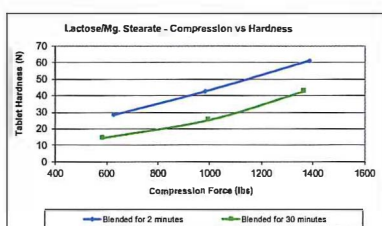


## Poor Tablet Formulation May Cause Erosion

- Tablets shown show uniform erosion.
- The formulation may not be ideal for producing robust cores under normal compression force.
- Swellable materials / disintegrants creating pinholes

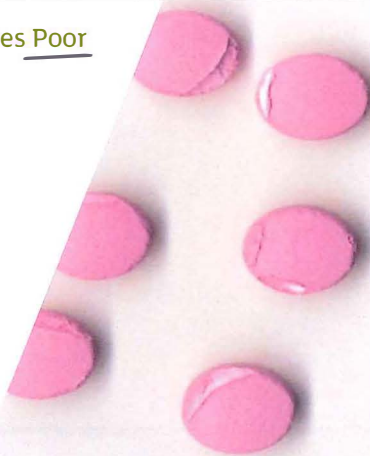


## Blending Time is Critical with Magnesium Stearate



### Excess Magnesium Stearate Causes Poor Coating

- Poor tablet hardness leads to erosion
- Excess lubricant creates adhesion issue - peeling



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### Tablets Need Time to Equilibrate Following Compression

- Tablets will expand slightly following compression
- This usually occurs within 24 hours.
- Cracking of the coating may occur if the tablet swells
- Swelling may also occur if the tablet absorbs water following coating (possible formulation issue with starch, MCC, other similar materials).



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Minimum wait 24 hrs after compression.

Questions?

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For Odor masking use Flavour help.  
Taste masking increase HPMC






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### Developing a Robust Coating Process

- The ideal coating process...
  - Is completed with minimal adjustments to parameters
  - Is reproducible with the same settings day after day
  - produces excellent tablets in high yield
- To create a robust coating process, it is necessary to...
  - Identify and properly set up **critical equipment**
  - Identify and optimize all **process parameters**
  - Start with excellent **core tablets**



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Critical equipment:

Gun to gun distance

Gun to pan distance

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### Tablet Film Coating – the basic process

- Coating is prepared as a liquid dispersion
- Liquid dispersion is pumped to a spray gun
- Spray gun spreads coating into a wide pattern of fine droplets and pushes it onto a moving tablet bed
- Drying air removes the liquid, leaving a smooth finished coating on the tablet



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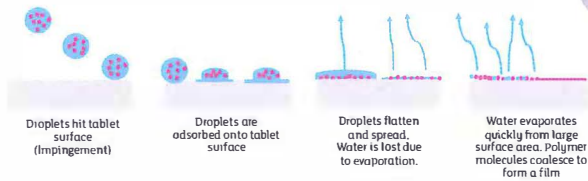
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## Factors Critical for a Uniform Coating



Note: The tablets are directly exposed to water...proper drying is critical to avoid moisture uptake by the tablets

## Factors Critical for a Uniform Coating

### Coating suspension

- Must be well dispersed to create a uniform appearance
- Should have low viscosity
  - Dispersion moves smoothly through the system without clogging
  - droplets reach tablet in suspension and then fully spread

### Pan Load and Pan Speed

- Slow enough to keep tablets from breaking
- Fast enough to get uniform mixing

### Spray rate / Spray pattern

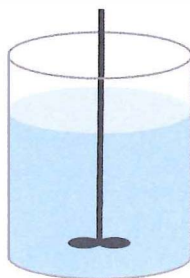
- Must be fast enough to cover tablets before they become damaged by coating process
- Pattern must be uniform to create uniform wetting
- Pattern must be wide to create an efficient process

### Drying air volume / drying air temperature

- Must be set to allow coating to dry very quickly once it spreads on the tablet

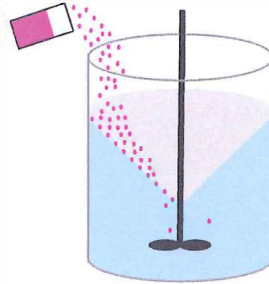
## Dispersion of SheffCoat™ Material

- Height of liquid in vessel ideally equals diameter of vessel
- Diameter of stirrer is approximately 1/3 diameter of vessel
- Low shear mixing is utilized; a minimal vortex is created



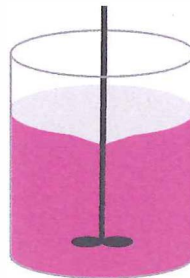
### Dispersion of SheffCoat™ Material

- Add powder slowly enough that it immediately is drawn into the vortex
- Increase speed as necessary to maintain vortex



### Dispersion of SheffCoat™ Material

- After powder is added and accepted by vortex, reduce stirring speed to create a minimal vortex. Ensure dispersion remains in continuous motion
- SheffCoat dispersion will be ready to spray in approximately 45 minutes
- Continue gentle stirring during spraying



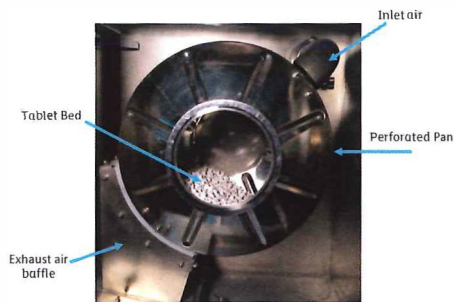
### Viscosity of Coating Suspension is a Critical Parameter

- Upper limit of viscosity is generally 200 cP for tablets with logo
- Upper limit of viscosity is generally 400 - 500 cP for tablets without logo
- Higher viscosity increases risk of spray drying / rough tablet surface





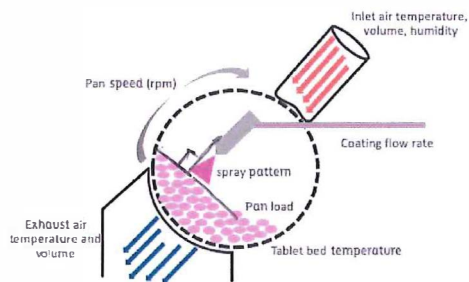
## Cross Section of a Typical Coater



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## Coating Process – Parameters to Control



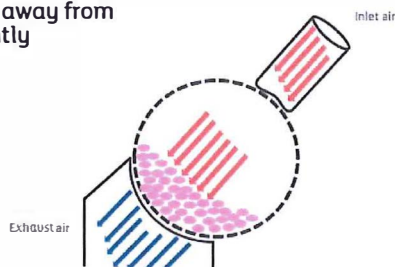
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90° between gun and tablets

## Pan Load is a Critical Parameter

- Drying airflow must pass **through** tablet bed, carrying water / solvent away from tablets efficiently



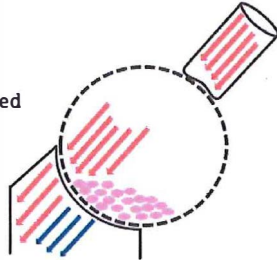
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Or less it will cause sticking

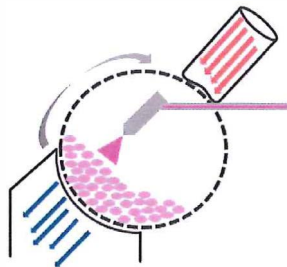
### Low Pan Load is Inefficient

- Airflow moves **over** rather than **through** tablet bed.
- Warm air is exhausted – inefficient process
- **overwetting** may occur with low drying efficiency
  - picking and sticking
  - tablet disintegration
  - Twinning
- Baffles must be covered by tablet bed



### Coating Process – Parameters to Control

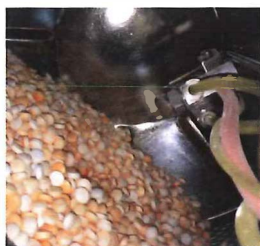
- The rotating pan moves tablets through the spray pattern, spreading the coating over a wide area.
- Low pan speeds may cause overwetting
- High pan speeds may cause tablet chipping
- Ideal pan speed is the lowest speed that creates a uniform tablet flow through the spray zone



Sharp edges tablets:

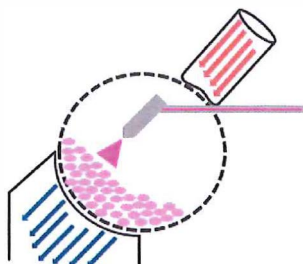
- 1) Slow spray pattern
- 2) Slow pan speed.

### Tablet to Tablet Variation in Color is Normal & Controllable



## Drying Air Parameters are Critical to Good Results

- Inlet and Exhaust air temperature and air volume are two key parameters
- Ideally Inlet air humidity is controlled
- A 10°C - 20°C difference between inlet air temperature and exhaust air temperature indicates a good evaporative process
- Majority of evaporation must occur from tablet surface for efficient process
- Overwetting can cause
  - Picking and sticking
  - Twinning



## Spray Distribution is a Critical Parameter

- For many coating pans, a 10°C - 20°C difference between inlet air temperature and exhaust air temperature indicates a good evaporative process
- If temperature difference is in this range, and problems with coating occur, they are often a result of uneven distribution of the spray on the tablet bed
  - Pan load
  - Pan speed
  - Type of spray gun
  - Number and spacing of spray guns
  - Gun-to-Bed distance
  - Variation in spray rates between spray guns
  - Droplet size (Atomization air pressure)
  - Pattern size and shape (pattern air)

## Coating droplet formation



- Coating suspension is pumped to a spray gun
- Atomization air breaks suspension into droplets
- Pattern air spreads droplets to form a spray "fan"
- The droplets are pushed by the air towards the tablets

### Spraying the Coating Dispersion – Pump Choice

- Peristaltic pumps deliver the most uniform flow of varying coating suspensions, making them ideal for most applications



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### Spraying the Coating Dispersion – Spray Gun Choice

- **Three Port Air Spray Gun** – inlet ports for
  - Atomizing air
  - Control air – controls needle which seals/cleans nozzle
  - Coating suspension
  - Some models have pattern air adjustment screws on the gun



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### Spraying the Coating Dispersion – Spray Gun Choice

- **Four Port Air Spray Gun** – inlet ports for
  - Atomizing air
  - Control air – controls needle which seals/cleans nozzle
  - Coating suspension
  - Pattern air

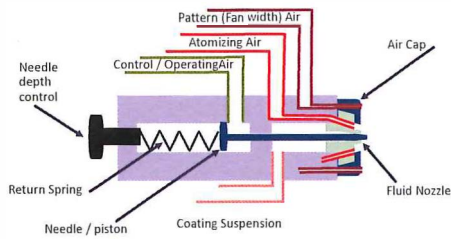


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Spraying the Coating Dispersion – Spray Gun



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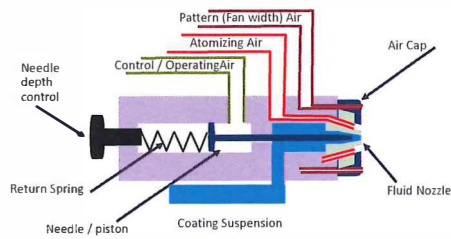
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The Needle is Opened and the Spray Gun Fills with Liquid



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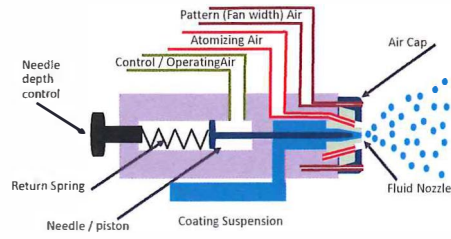
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Air Pressure Converts Liquid to a Fan of Droplets



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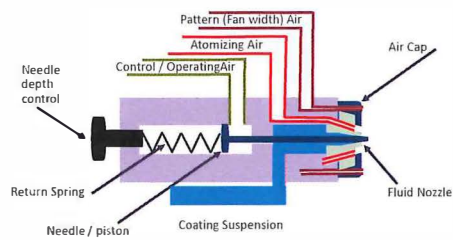
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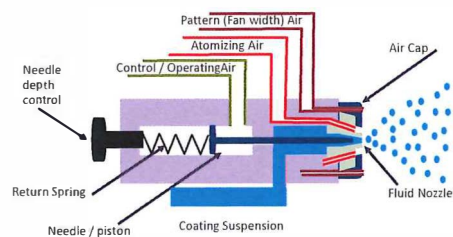
## Spray Gun Goes Through Clean Cycle when Needle Closes



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## Spray Resumes when Needle Retracts

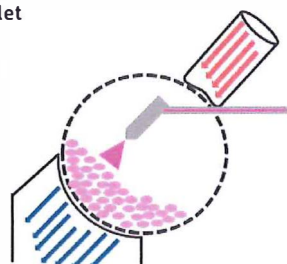


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## Spray Gun Distance is a Critical Parameter

- **Spray gun is set correctly**
  - Spray gun is at 90° to tablet bed
  - Spray gun is aimed at bottom of cascade / upper third of tablet bed
  - Fine droplets hit tablet bed, smooth, and dry

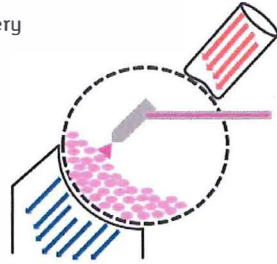


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## Minimal Gun-to-Bed Distance Causes Overwetting

- **Spray gun is too close to tablet bed.**
  - Spray is concentrated in a very small area
  - Overwetting occurs

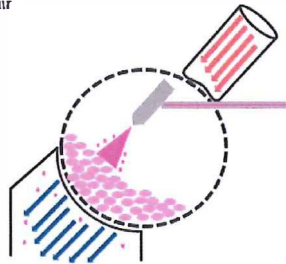


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## Excessive Gun-to-Bed Distance Causes Overdrying

- **Spray gun is too far from tablet bed.**
  - Spray is exposed to excessive drying air en route to tablet bed
  - Spray drying occurs
    - Rough tablets are seen
  - Inefficient process
    - Tablet erosion
    - loss of coating dust via exhaust



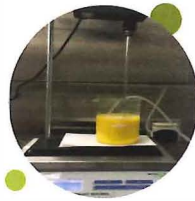
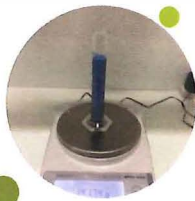
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## Spray Gun Flow Rate is a Critical Factor



Measure flow per gun to get totalspray rate and confirm multi-gun setups are balanced



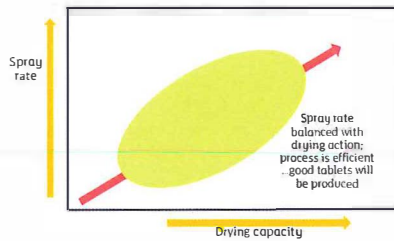
Measuring flow for a single gun set-up on a balance

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### Setting the Spray Rate is Critical to Obtaining Good Tablets

- There is a balance between drying capacity and spray rate
- a wide variety of spray rates can be used to produce good tablets, as long as the drying capacity is adjusted to match



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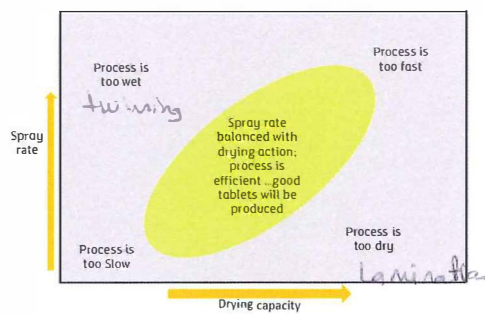
KERRY

high spray rate & low drying capacity → lamination  
twinning.

high temp. & low spray rate → lamination.

low temp & low spray rate → take along time.

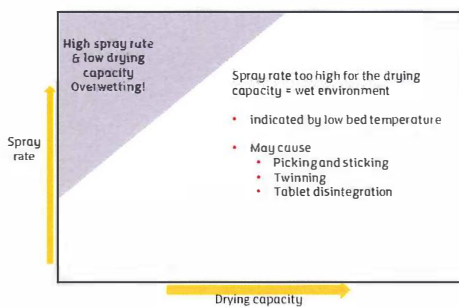
### Setting the Spray Rate is Critical to Obtaining Good Tablets



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### Overwetting Occurs when Spray Rate Exceeds Drying Ability

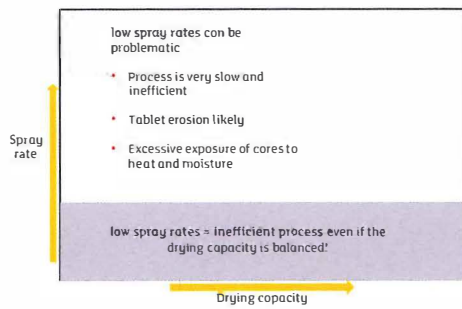


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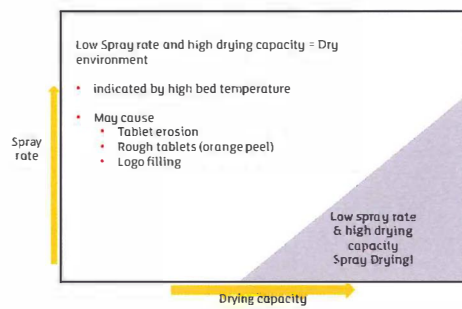
KERRY



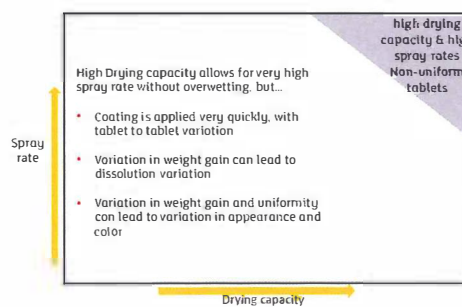
## Low Spray Rate = Inefficient Coating Environment



## Spray Drying Occurs in a Very Dry Coating Environment



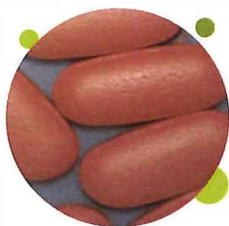
## High Spray Rate & High Drying = Applying Coating Too Quickly



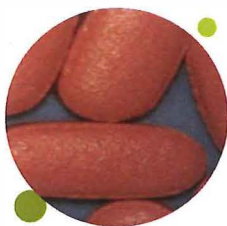
## Determining Optimal Spray Rate & Parameter Limits

Multiple trials with varying spray rates, temperatures, and % solids can be performed to determine process limits

- Significant data regarding tablet appearance is immediately visible
- Stability data may be moisture dependent – longer process



ibuprofen tablets – successful trials



ibuprofen tablets – failing trial conditions too wet!

## Determining Effect of Moisture on Tablets/Optimal Spray Rate & Parameter Limits

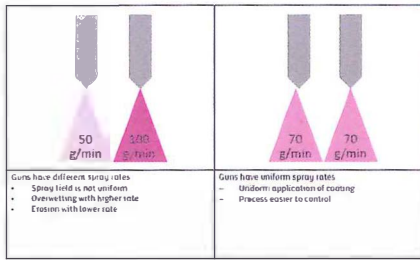
Trial	Temperature	Spray rate	% Solids	Pass/Fail	Notes
1	38	6	15	Pass	
2	60	6	15	Pass	
3	38	9	15	Pass	Wettest environment successful
4	60	9	15	Pass	
5	38	6	20	Pass	
6	60	6	20	Pass	
7	38	9	20	Pass	
8	60	9	20	Pass	
9	38	6	22.5	Pass	
10	60	6	22.5	Pass	
11	38	9	22.5	Pass	
12	60	9	22.5	Pass	
13	38	6	25	Pass	
14	60	6	25	Pass	Driest conditions successful
15	38	9	25	Pass	
16	60	9	25	Pass	
17	45	7	30	Pass	Conclusive trial
18	35	9	15	Fail	Wettest conditions attempted

## Uniform spray patterns make uniform tablets

- Multi-gun spray bars need to make a uniform pattern that does not overlap or have gaps
  - Guns spaced correctly
  - Patterns adjusted correctly
  - Coating suspension evenly distributed between guns



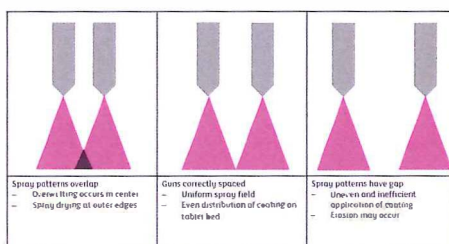
## Balanced Flow of Coating is a Critical Parameter



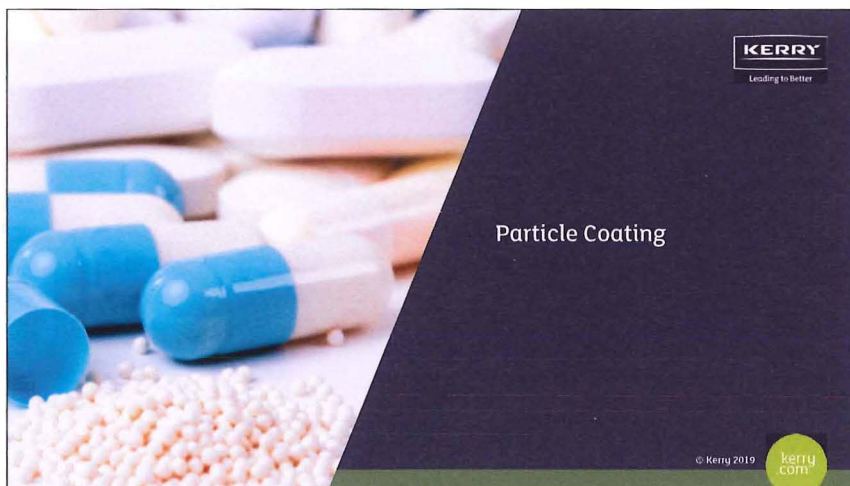
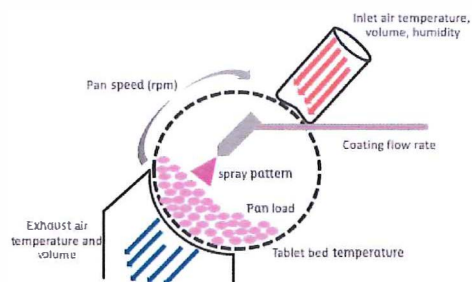
## Balancing Flow Between Spray Guns

- Best practice is to measure the flow from each individual gun
- Pressure differential across spray manifold may result in uneven distribution
- Separate pumps allow different pump speeds for different guns

## Distance Between Spray Guns is a Critical Parameter



## Coating Process – Parameters to Control



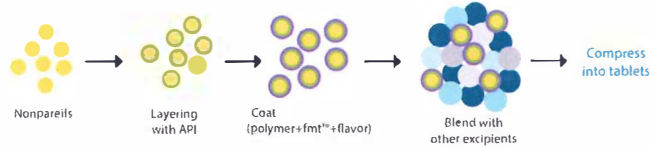
## Particle Coating

## Particle Coating

- Many APIs are delivered in small particles or granules
- These particles can be delivered in sachets, placed in capsules, or tableted
- Advantages to using particles
  - Control release (particularly useful in multi drug forms)
  - taste masking of bitter drugs
  - Poorly compressible drugs can be layered on sugar spheres
  - Separation of sensitive APIs



## Formulating an ODT MUPS

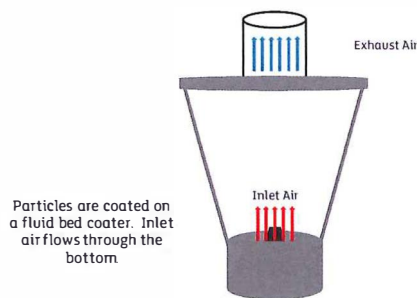


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Disintegricks Mcc

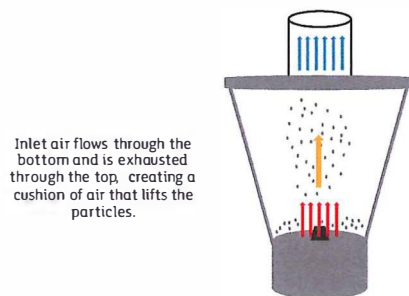
## Fluid Bed Coater – Typical Design



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## Particles are Lifted on a Cushion of Air in a Fluid Bed Coater

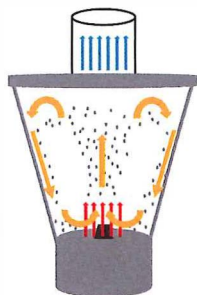


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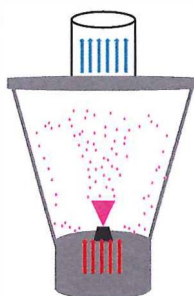
## Movement of Particles in a Fluid Bed Coater

When the particles approach the top of the coater, they fall along the sides to the bottom and are returned to the air stream



## Particle Flow Through the Spray Fan in Fluid Bed Coater

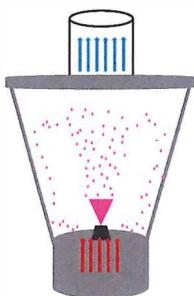
Flow of particles through coating spray – similar in some ways to a bed of tablets moving through a coating spray



## Fluid Bed Coater Parameters are Similar to Pan Coater

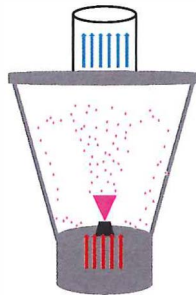
Parameters to Control  
(very similar to tablet coating)

- Airflow (volume)
- Inlet air temperature / humidity
- Particle load
- Spray rate
- Atomization air
- Pattern air
- Dispersion % solids (viscosity)



## Additional Considerations with a Fluid Bed Coater

- Static charge becomes a factor – particles may stick together during and after coating
- Weight gains are typically higher, due to a higher surface to mass ratio



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Fluid bed coater used  
for pellets coating

Questions?

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Leading to Better

SheffCoat™ SG:  
Coating for Soft Gel Capsules

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What are the challenges faced by soft gel manufacturers and marketers?

- Lack of Shine
- Lack of Stability
- Bad Odor
- Convincing pediatric patients

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### Soft Gel Film Coating Challenges

- Compatibility of ingredients
- Migration of ingredients into soft gel filling
- Over plasticizing delaying in bio-availability
- Flavour compatibility
- Process Parameters

Coating soft gel capsules provide moisture barrier to increase stability in hot and humid regions.



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### ShelCoat™ SG

- PVA based, low temperature film coating for soft gel capsules.
- Providing enteric, sustained release and moisture protection functionality.
- Enabling delicate coating, enhancing therapeutic performance and improving patient experience



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## Ingredients & Process Parameters



Compatibility



Migration



Stability



Temperature  
(Inlet, Bed & Outlet)

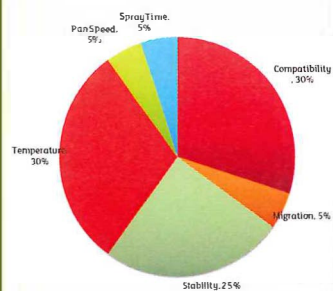


Pan Speed



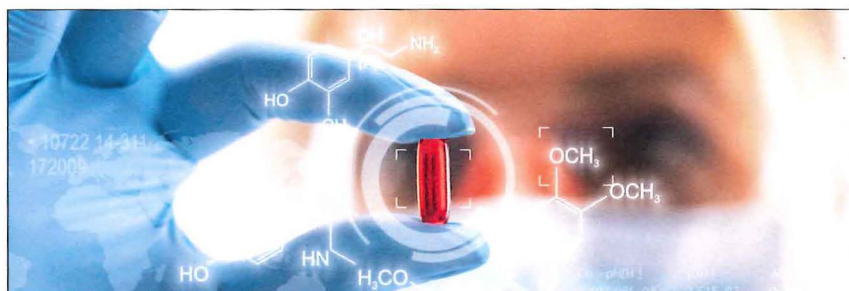
Spray Time

### Factors Depending on Formulating Film Coating – Soft Gel Capsules



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## Ingredients Selection

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## Employing CAST Approach – Polymer Selection

PVA was selected among available industry standard polymers



**C**ost

Less expensive: cutdown ~10%



**A**queous

Environment friendly & healthy solvent



**S**tability

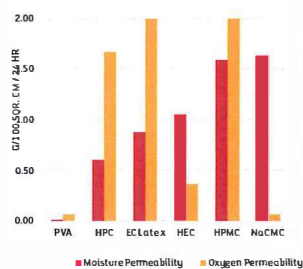
Has least moisture and oxygen permeability



**T**ime

Enables high solid content (20%)

### Water and Oxygen Permeability



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### Selection of Ideal Plasticizers

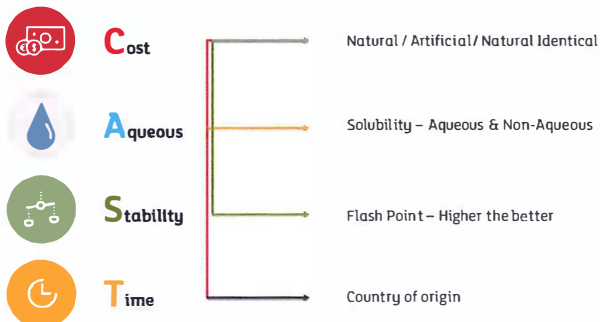
- It is very important to choose right plasticizer ideal for film coating
- We choose PEG 6000 because
  - Compatible with cassava starch capsules
  - Moisture Protection (Increase in MW).
    - (increase in MW increases moisture protection)
  - Good Plasticizing capabilities

### Selection of Set of Pigments

- It is very important to include pigments even if soft gel capsules are already coloured.
- A clear film coating will cut down the intensity of the colour.
  - PVA Clear film coating will cut down the shade of capsules
- We choose Pigments because
  - Matching the color
  - Avoid dull finishing

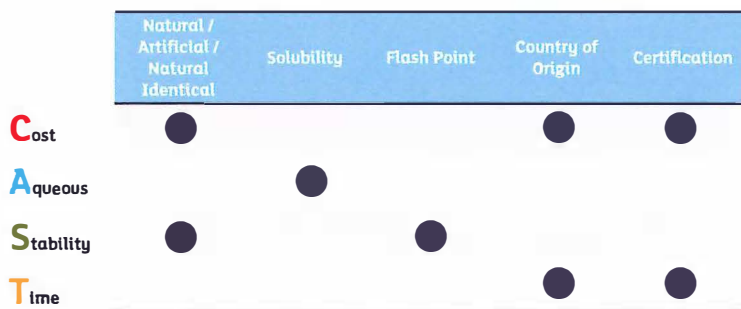


### Selection of Flavours – Key Criteria – CAST Approach



Flavours are sensitive to temp.

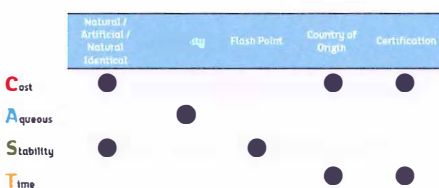
## Selection of Flavours – Key Criteria – CAST Approach



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## Example of Flavour Selection by Customer & Kerry R&D



Based on CAST Approach

1. According to heat resistance, below sample requested by the customer.

Flavour	Code	Manufacturing site	Legislation	Halal status	solubility	Flash point
Lemon Lime F-07864	20122295	Grasse	NAT	Suitable	w/s	>93
Lime Natural CFN4395	20422809	India	NAT	Suitable	w/s	>70
Mint Spearmint 1446	20422258	India	NI	Suitable	w/s	>70
Lemon F2020	20422423	India	NI	Suitable	w/s	>70

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## Kerry Product Matching Tool

Drug Categories	Suitable API	Kerry Solution
Health Supplements	Multivitamins Ginseng Omega 3 Fish Oils Iron & Folic Acid	<ul style="list-style-type: none"> <li>SheffCoat™ Soft Gel</li> <li>Polymer: PVA</li> <li>Plasticizer: PEG 6000</li> <li>Solvent: Water</li> </ul>
Nonsteroidal Anti Inflammatory Drugs (NSAIDs)	Ibuprofen	<ul style="list-style-type: none"> <li>SheffCoat™ Soft Gel</li> <li>Polymer: PVA</li> <li>Plasticizer: PEG 6000</li> <li>Solvent: Water</li> </ul>
Pain Killers	Isotretinoin	<ul style="list-style-type: none"> <li>SheffCoat™ Soft Gel</li> <li>Polymer: PVA</li> <li>Plasticizer: PEG 6000</li> <li>Solvent: Water</li> </ul>

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## Coating Process

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## Precautions & Pre-Coating – SheffCoat™ PVA Green 5Y02055

### Process Related Information

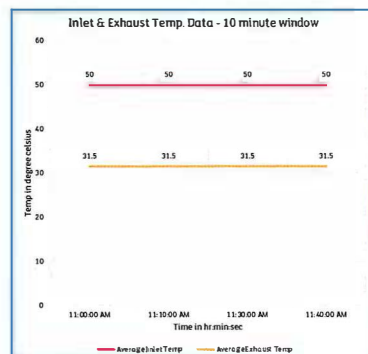
Machine & Materials	SheffCoat™, Solvent & Dispersion	Precautions
<ul style="list-style-type: none"> <li>Machine                             <ul style="list-style-type: none"> <li>Conventional Pan – 9"</li> <li>No of Baffles – 3</li> <li>No of Spray Guns – 1</li> </ul> </li> <li>Materials                             <ul style="list-style-type: none"> <li>SheffCoat™ PVA Green 5Y02055</li> <li>De-mineralized Water</li> <li>Nylon Cloth # 100</li> <li>Conventional Pan Coater</li> <li>Spray Gun</li> <li>Uncoated Soft Gel Capsules</li> </ul> </li> </ul>	<ul style="list-style-type: none"> <li>15g of SheffCoat™ in 60g of DM Water.</li> <li>Reconstitution Level – 20% w/w <i>PVA</i></li> <li>Stirring Time – 45 minutes</li> <li>Dispersion filtered thru – Nylon Cloth #100.</li> <li>Batch Size – 500 g                             <ul style="list-style-type: none"> <li>Uncoated Soft Gel Capsules</li> </ul> </li> <li>Avg wt of 10 uncoated capsules – 6.6178 g</li> </ul>	<ul style="list-style-type: none"> <li>Sort out leaking capsules                             <ul style="list-style-type: none"> <li>leaking capsules may cause bad odor of whole batch.</li> </ul> </li> <li>Start slowly – low pan speed;                             <ul style="list-style-type: none"> <li>few capsules may stick pan surface.</li> <li>few capsules may break open. Pick them out.</li> </ul> </li> </ul>

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## In-Process Parameters – Temperature – Inlet & Exhaust

- At high temperature, cassava starch has better strength over bovine gelatine.
  - Maintain inlet temperature at 50°C
  - Ensures the capsule seal is not negatively impacted.
- Maintaining temperature within 50°C ensures stability of flavour (if applied in film coating)
  - Water soluble flavors with flash point 30°C to 75°C are fairly stable.
  - Oil soluble flavors has higher flash point but cannot be considered in aqueous film coating.

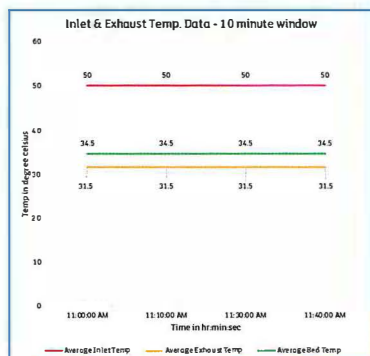


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## In-Process Parameters – Temperature – Bed Temp

- Bed Temperature is maintained 30% below inlet temperature.
  - Ensures capsule seal is not affected.
  - Flavor (if used) is stable
- Capsules have tendency to absorb some temperature thus the exhaust temperature is lower than bed temperature.
  - This will not have a greater impact on the stability of capsule fill.



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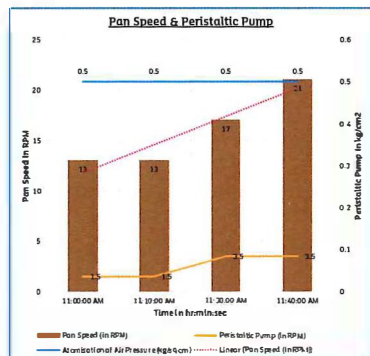
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\* In Film Coat for tablets.  
outlet temp ~~less~~ than tablet  
Bed higher

\* In Capsules  
outlet temp less than  
tablet Bed.

## In-Process Parameters – Pan Speed & Peristaltic Pump

- Pan Speed
  - Initiate the process with slow pan speed to avoid sticking of capsules on the surface of coating pan.
  - A linear trend increase in pan speed assists in ensuring capsules are intact.
- Atomisation of Air Pressure
  - consistent at 0.5 kg/cm<sup>2</sup> across the trial.
- Peristaltic Pump
  - This pump was synchronized with pan speed to ensure capsules don't get punctured / break open



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## Weight Gain Analysis

- A slow start (pan speed & peristaltic pump);
  - to reduce the friction between capsules & pan.
- First 10 minutes – 0.0695% weight gain only.
- 20 minutes later (@ 30 minutes) – 1.7996% weight gain
- 20 minutes later (@ 40 minutes) – 2.2998% weight gain

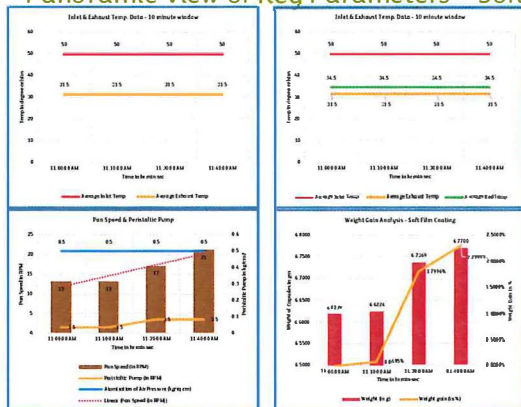


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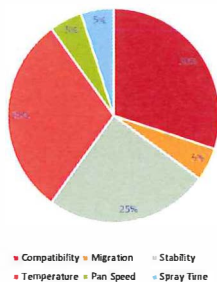
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## Panoramic View of Key Parameters – Soft Capsules



### Factors Depending on Formulating Film Coating – Soft Gel Capsules



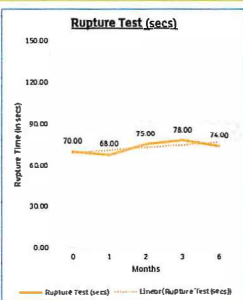
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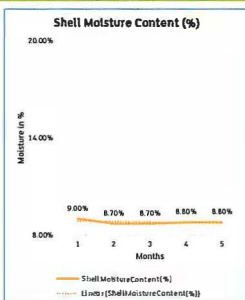
## Stability Data of Film Coated Soft Capsules

### Key Parameters

#### Rupture Test Results



#### Shell Moisture Content



#### Microbial Enumeration

Months	0	6
TAMC	< 1000 cfu/g	< 1000 cfu/g
TMYC	< 100 cfu/g	< 100 cfu/g
E. Coli	Negative	Negative

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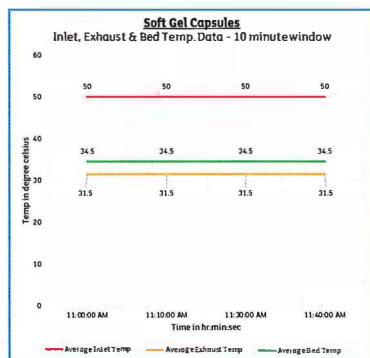
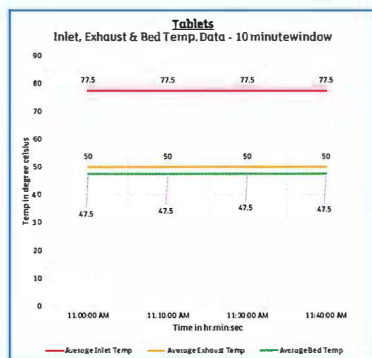
## Film Coating Parameters

### Tablets Vs Soft Gel Capsules

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## Bed Temp for Tablets vs Bed Temp for Soft Gel



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## Tablet Film Coating Vs Soft Gel Film Coating

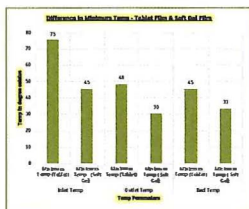
Temperature Related Differences

Tablet Film VS Soft Gel Film

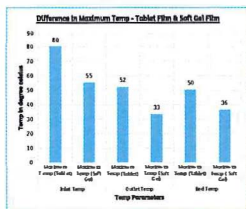
Tablet Film VS Soft Gel Film

Tablet Film VS Soft Gel Film

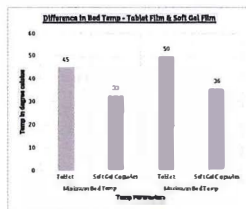
### Difference in Minimum Temperatures



### Difference in Maximum Temperatures



### Difference in Bed Temperatures



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Questions?

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## Kerry Leads in Clean Label Solutions

At Kerry, we see our customers solve clean label challenges in many ways from **reducing and simplifying ingredient statements**, to entire brand repositioning.

Explore the many ways we can help you **create clean label solutions** that meet your consumer's needs.

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41%

Ingredients influence 41% of consumers' clean label expectations

70%

Nearly 70% of ingredient conscious consumers read a product's nutritional panel before purchasing

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## Many different requirements for clean labels

- Artificial colorant free
  - Aluminum lake free
  - Carmine free
  - Iron oxide free
- Titanium dioxide free
- Nothing on Whole Foods banned list – inc Polydextrose
- Talc free
- Allergen free

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## Changing regulations limit color choices

- EFSA undertaking review of iron oxides
- France proposing ban on titanium dioxide in food ingredients
- FD&C Yellow #5 requires a label for drugs in the US (link to hyperactivity in children)
- Limits in place on amounts of many aluminum lake colors in a number of regulatory regions

## Artificial Colors were developed to increase stability

- Artificial colors were developed to provide a consistent, stable, and often vibrant color for consumers.
- This defined consumer expectations of what a product should look like, and how it should perform.

### Titanium Dioxide



- Creates a white coating
- Acts as opacifier for other colored coatings
- Insoluble pigment

### Artificial Dyes & Lakes



- Highly regulated, often batch certified
- Lakes are insoluble
- Dyes are water soluble

### Iron Oxides



- Red, yellow, and black
- Provide color and opacifying ability at the same time
- Insoluble pigment

## Natural Colors

- Multiple options, many plant derived
  - Vegetable juice
  - Turmeric oleoresin
  - Spirulina
  - Beta-carotene



## Natural Color concerns

- Spirulina
  - poor suspension stability/Reactive with core ingredients (fades)
  - High raw material cost
- Turmeric
  - Forms red precipitate at high pH– causes speckling
- Riboflavin
  - Fluorescent light stability concern
  - Taste off-notes at higher use levels
  - Opacity concerns
  - Chemically synthesized material is less expensive option than that isolated from nature
- Vegetable Juice
  - Minimal color choices at higher pH (slate blue)
  - More stable color option

Using CaCo<sub>3</sub> instead of  
Titanium Dioxide.

## Translucent Coating Option

- Remove and do not replace titanium dioxide; utilize natural colorants
- More vibrant colors achieved
- Spot formation on stability becomes concern with Multivitamin/minerals
  - Mitigated by color choice and darkness
- Natural color choice becomes key indicator of stability
- HPMC/HPC is excellent polymer option. Elimination of additional plasticizer improves stability.

## SheffCoat™ TF Purple 30749755

- Very clean label
- Shiny, uniform coverage with 2.7% weight gain (multivitamins)
- Stability (accelerated conditions) similar to artificial color options



Ingredient	EN
Hydroxypropylmethylcellulose / Hypromellose, type 2910, (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
color -anthocyanin	E163
Spirulina Extract	

Titanium Free



SheffCoat™ TF Blue 30752596

- Very clean label
- Shiny, uniform coverage with 2-3% weight gain (multivitamins)
- Stability (accelerated conditions) similar to artificial color options
- Clean label option to indigotine aluminum lake



Ingredient	E#
Hydroxypropylmethyl cellulose / Hypromellose, type 2910 (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
color anthocyanins	E163
Spirulina Extract	

SheffCoat™ TF Pink 30752591

- Very clean label
- Shiny, uniform coverage with 2-3% weight gain (multivitamins)
- Clean label option to carmine



Ingredient	E#
Hydroxypropylmethyl cellulose / Hypromellose, type 2910 (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
Citric Acid Monohydrate (USP, EP)	E330
color anthocyanin	E163

SheffCoat™ TF Orange 30752598

- Very clean label
- Shiny, uniform coverage with 2-3% weight gain (multivitamins)
- Clean label option to Sunset Yellow aluminum lake



Ingredient	E#
Hydroxypropylmethyl cellulose / Hypromellose, type 2910 (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
Citric Acid Monohydrate (USP, EP)	E330
Turmeric Oleoresin (color)	E100
color anthocyanin	E163

## Options for Titanium replacement

- calcium carbonate
  - Best option in terms of index of refraction
  - Lower risk of scuffing
  - Some forms make suitable detackifiers
  - Selection of proper crystal shape / size improves opacity
- Rice starch
  - Poor opacity and poor film characteristics
- tricalcium phosphate
  - Lower index of refraction (poor opacity)
  - Scuffing potential higher than cal carb

## SheffCoat™ TF coatings for changing regulatory and consumer requirements



SheffCoat TF 30739358

SheffCoat White  
(titanium dioxide)

## Improving efficiency without polysaccharides



- SheffCoat TF 30748443, applied to multivitamins to 4.5% weight gain
- HPMC, PVA, HPC, calcium carbonate

## SheffCoat™ TF Green 30749712

- Opaque coverage of multivitamins at 4% weight gain
- Clean label alternative to aluminum lakes and sodium copper chlorophyll



Ingredient	E#
Calcium Carbonate (USP, EP, FCC)	E170
Hydroxypropylmethylcellulose / Hypromellose, type 2910, (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
Turmeric Oleoresin (color)	E100
Spirulina Extract	

## SheffCoat™ TF Yellow 30749718

- Opaque coverage of multivitamins at 4% weight gain
- Clean label alternative to yellow iron oxide or tartrazine aluminum lake



Ingredient	E#
Calcium Carbonate (USP, EP, FCC)	E170
Hydroxypropylmethylcellulose / Hypromellose, type 2910, (USP, EP, JP)	E464
Hydroxypropylcellulose (USP, EP, JP)	E463
Turmeric Oleoresin (color)	E100
Riboflavin	E101(i)

## Improving efficiency without polysaccharides

- Polydextrose typically used to maximize efficiency (viscosity modifier); ingredient not permitted by Whole Foods
- Use polyvinyl alcohol / HPMC as dual polymer system for increased efficiency
- Can be utilized with translucent or opaque options
- Use of dual polymers eliminates need for talc
- Stability similar to HPMC/HPC option.
- Is PVA acceptable from label standpoint?

## SheffCoat™ TF Blue

- Opaque coverage of multivitamins at 4% weight gain
- Applied at 18% solids
- Clean label alternative to indigotine aluminum lake



Ingredient	E#
Calcium Carbonate (USP, FCC)	E170
Hydroxypropylmethylcellulose / Hypromellose, type 2910, (USP, EP, JP)	E464
Hydroxypropyl cellulose (USP, EP, JP)	E463
color anthocyanin	E163
Spirulina Extract	

## SheffCoat TF with calcium carbonate is stable over time

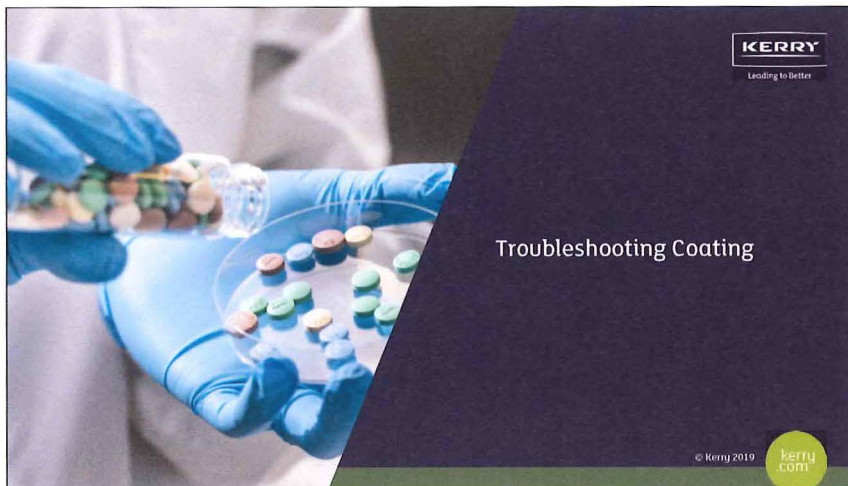
- Utilize mixed polymer base to minimize spot formation and material migration
- Formulate to utilize high levels of calcium carbonate for maximum opacity at minimum weight gain

Color	Colorants / other ingred	3 day open dish, Eab	Light stability	24 hour light stability
Blue	Vegetable juice / spirulina / calcium carbonate	8 - 12	2-8	<1.5
Yellow	riboflavin/turmeric/ calcium carbonate	15-20	15-20	4+
Green	Spirulina / vegetable juice/ Turmeric / Calcium carbonate	8-12	5-10	<3

## Summary of options

	HPMC / HPC	HPMC/HPC/ Cal carb	HPMC/ HPC/ PVA	HPMC/ HPC/PVA / Cal Carb
Color options	***	**	***	**
Process time	**	*	***	**
stability	**	***	**	***
Film performance	***	**	***	**
Cost in use	***	*	***	**

Questions?



### Picking & Sticking

- Picking occurs when two surfaces of a tablet stick together from the coating as it dries and then pulls apart... (Very similar to tablet twinning)
- Increase pan speed to decrease contact time / decrease amount of tablet wetting
- Reduce overwetting
  - decreasing spray rate
  - decrease droplet size / increase atomization
  - increase drying (air volume or temperature)





### Spray Drying / Surface Roughness

- Spray drying occurs when a droplet is partially dried while en route to the tablet
  - This is loss of efficiency!
- Decrease gun to bed distance
- Decrease drying efficiency
  - Lower temperature
  - Lower volume
- Increase droplet size (decrease atomization)
- Decrease suspension viscosity – have more water per droplet

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### Cracking

- Tablet cracking occurs when the film is not strong or elastic enough
- Select a stronger polymer/blend for the coating
- Increase level of plasticizer
- Reduce pan speed / change baffles
- Increase time between compression and coating to allow tablet to "relax"
- Minimize heat of coating - select polymer that can be applied at lower temperature conditions

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### Tablet Coating Peeling

- Improve adhesion by changing formulation of tablet (excess lubrication in blend can cause this)
- Change coating formulation to improve adhesion and/or strength – change polymer type or amount (adhesion - addition of HPC or change to PVA)

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HPMC is good for mechanical strength & elasticity

### Tablet Twinning

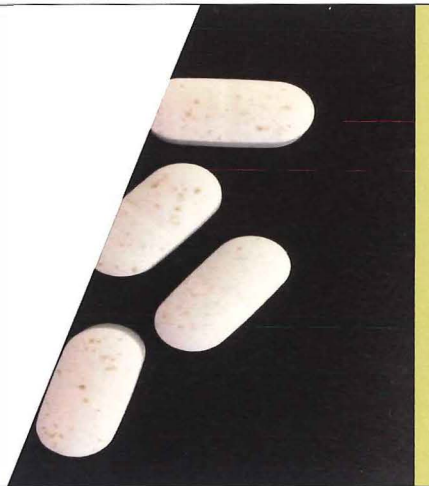
- Tablet twinning occurs when two flat surfaces of a tablet are "glued" together by the coating as it dries...caused by
  - Flat faces of tablets coming in contact
    - Prevent by changing shape of tablet – curves instead of flats
    - Increase pan speed to decrease contact time
  - Coating is drying too slowly
    - Lessen the chances by decreasing spray rate



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### Spotty Tablets

- Tablet spots can occur if material in the core is visible through the tablet film
- Increase opacifiers (pigments) in coating
- Increase weight gain of coating
- Spots that develop over time may indicate migration of ingredients
  - Change coating formulation to prevent migration
- Development of spots over time may indicate that a material is degrading
  - Increase oxygen and/or moisture protection of coating



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### Tablet Edge Chipping

- Edge chipping occurs when the tablet coating is not able to protect soft edges of the tablet as they contact the coater or other tablets
- Apply a stronger and more elastic coating
- Apply coating more quickly
  - Increase spray rate
  - Increase solids in spray suspension
- Decrease pan rotation
- Change baffles



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- Change punch sharpness

### Tablet Erosion

- Tablet erosion occurs when the tablets are too soft / friable
- Compress harder tablets
- Lubricant levels / overblending may be a cause
- Coat tablets more quickly
  - Eliminate spray drying
  - Utilize faster spray rates
  - Utilize higher % solids



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### Using Coatings to Improve Dissolution Profile

- Factors that will influence dissolution profile
  - Tablet hardness
  - Tablet uniformity – including uniformity of coating
  - Polymer used in coating / coating choice
  - Coating thickness (weight gain of coating applied)
- Proper selection of a tablet coating can help to change dissolution profile...often enough to make the difference between passing and failing  $f_1$  and  $f_2$  comparisons.
- This can be particularly useful if the core formulation is already set, or if a 2 or 3 API dose form is being developed and one or more of the APIs already has a favorable dissolution.

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### Decreasing Dissolution Rate / Increasing Time to Dissolve

- **Core Modifications**
  - Decrease amount of disintegrant
  - Compress harder tablets
- **Coating modifications** – two factors contribute to coating dissolution – polymer choice / blend and coating weight gain
  - Utilize a polymer/blend that will dissolve more slowly
    - HPC is slower than HPMC – utilize as a secondary film former
    - EC does not dissolve – utilize as a secondary film former if possible to do solvent coating
    - Utilize hydrophobic plasticizers
  - Add a higher coating weight gain or utilize more polymer and less pigment

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## Increasing Dissolution Rate / Decreasing Time to Dissolve

- **Core Modifications**

- Add / increase amount of disintegrant
- Compress softer tablets

- **Coating modifications** – two factors contribute to coating dissolution – polymer choice and coating weight gain

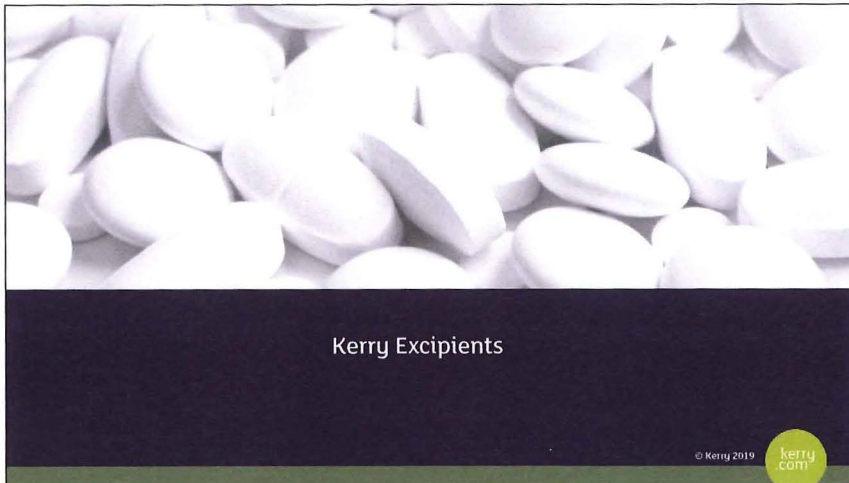
- Utilize a polymer/blend that will dissolve more quickly

- PVA faster than HPMC faster than HPC.
- EC does not dissolve – remove if possible

- Add a lower weight or utilize less polymer and more plasticizer and pigment

Questions?

Questions?




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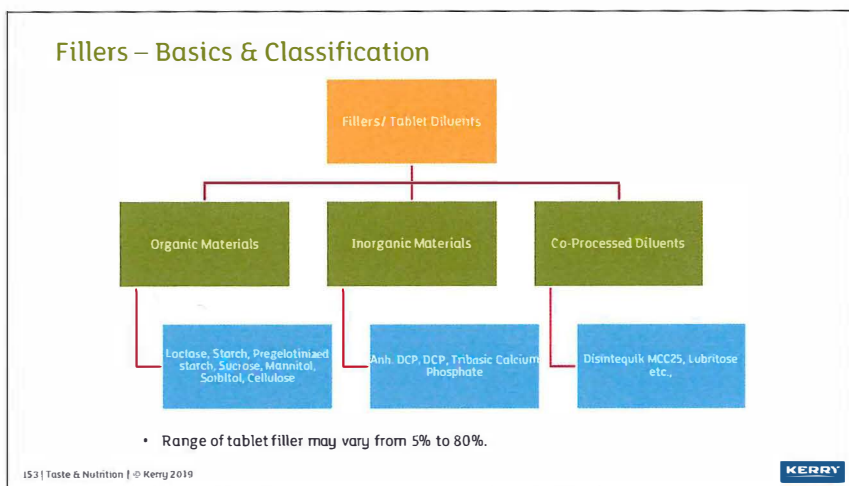
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### Classification of Diluents Based On Their Solubility

Insoluble Tablet Filler or Diluents	Soluble Tablet Filler or Diluent
Starch	Lactose
Powdered Cellulose	Sucrose
Microcrystalline Cellulose	Mannitol
Calcium Phosphate	Sorbitol

*Handwritten notes:*  
 Lactose: good to dissolution  
 Mannitol: Best one

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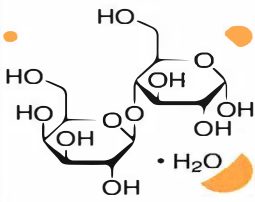
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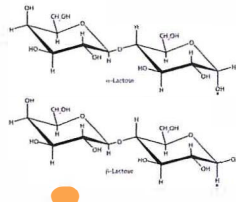
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## Lactose Monohydrate - Chemistry



Made up of Glucose & Galactose  
Presence of a water molecule



ANOMERS - Alpha & Beta Lactose  
Muta-rotation - Change in orientation of H & OH group on a specific carbon atom on glucose moiety



Beta anomer is 7-fold more soluble than alpha anomer.  
Alpha Lactose has pure alpha-anomer crystals & minor beta-anomer crystals.  
Beta Lactose has pure beta-anomer crystals.

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$\beta$ -lactose has extremely higher solubility than  $\alpha$ -lactose

Anhydrous Lactose containing >70%  $\beta$ -Lactose  
Used for: Better dissolution.  
Compressibility.

## Forms of Lactose

- Lactose exists as monohydrate or anhydrous
- Each form also is made up of alpha and beta anomers
- The % of alpha and beta content is dependant on solution and drying conditions

### Crystalline Monohydrate

- Nearly 100% alpha crystals (low amorphous content)
- Not compressible and low dissolution (must be granulated)

### Anhydrous

- Mixture of alpha and beta lactose
- Contains high beta content (>70%)
- Allows for high compressibility and solubility

### Spray Dried

- Mostly alpha but contains some amorphous
- Amorphous acts like glue to hold crystals in spherical form
- Amorphous allows for high compressibility and solubility but shorter shelf life



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Very good  $\alpha$   $\rightarrow$  very good compressibility.

Spray dried  $\rightarrow$   $\alpha$ -Lactose but granules.

## Kerry's Lactose Product Range

Crystalline Monohydrate	Spray Dried Monohydrate	Anhydrous Lactose	Inhalation Lactose	Modified Spray Dried, Agglomerated
Shelfield <sup>®</sup> Capsulating Grade	Foremost <sup>®</sup> 315	Shelfield <sup>®</sup> DT	AeroFlo <sup>™</sup> b5 Monohydrate	AeroFlo <sup>™</sup> B5S, Anhydrous
Shelfield <sup>®</sup> 60M	Foremost <sup>®</sup> 316 Fast Flo <sup>®</sup>	Shelfield <sup>®</sup> 60M	AeroFlo <sup>™</sup> 55 Monohydrate	ReddFlo <sup>®</sup> BAC
Shelfield <sup>®</sup> 200 Mesh		Shelfield <sup>®</sup> Impalpable	AeroFlo <sup>™</sup> 35 Monohydrate	
Shelfield <sup>®</sup> Impalpable			AeroFlo <sup>™</sup> 25 Anhydrous	
Foremost <sup>®</sup> 310				
Foremost <sup>®</sup> 312				
Foremost <sup>®</sup> 313				

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DTHV

Direct tableting high Velocity.

## Crystalline Monohydrate – Milled Lactose

- Unique manufacturing process:
  - Enhances stability
  - Maintains crystalline form
  - Used for wet or dry granulation

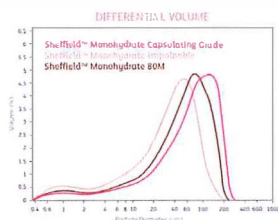
		Application	
Improved binding Improved flow	Foramect® Brand Monohydrate 310	Wet or dry granulation (coarse)	Coarse ↓ Fine
	Sheffield™ Brand Monohydrate Capsulating Grade	Wet or dry granulation (medium)	
	Foramect® Brand Monohydrate 312	Wet or dry granulation (medium)	
	Sheffield™ Brand Monohydrate 80M	Wet or dry granulation (medium/fine)	
	Sheffield™ Brand 200 Mesh	Wet or dry granulation (fine)	
	Sheffield™ Brand Monohydrate Insoluble	Wet or dry granulation (fine)	
	Foramect® Brand Monohydrate 313	Wet or dry granulation (fine)	

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Kerry → Five years shelf life.  
Other 2-3 years.

## Sheffield™ Crystalline Monohydrate



Monohydrate Insoluble



Monohydrate 80M



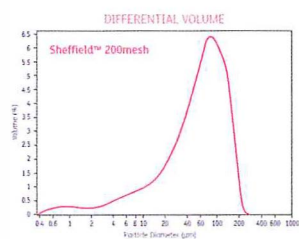
Monohydrate Capsulating

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Finest  
grade.

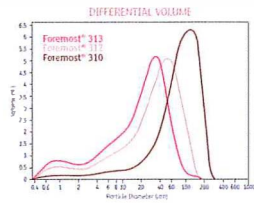
## 200 Mesh: Particle Size



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## Foremost™ Crystalline Monohydrate



Monohydrate 313



Monohydrate 312

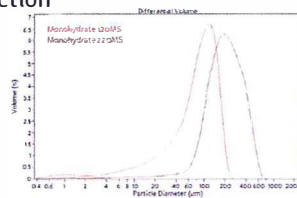


Monohydrate 310

## Crystalline Monohydrate – Sieved Lactose

- Narrow particle size distribution
- Have typically a tomahawk shape
- Good flow
- Behave brittle during compaction
- Moderate binding properties

Alpha monohydrate lactose could be sieved after crystallisation. This result in more narrow particle size distribution



US: Milled and Sieved.

## Crystalline Monohydrate – Milled & Sieved

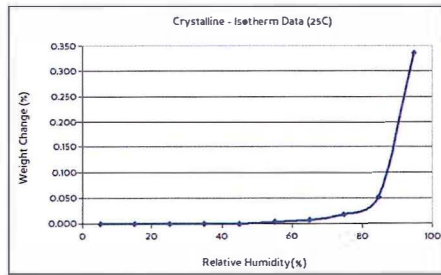
Below list of different grades of Lactose Monohydrate manufactured at our site in India

Product Name
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF Impalpable HPI
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 80Mesh
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 200Mesh*
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF DC2050
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 100Mesh
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 120Mesh
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF DC60
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 270M
Sheffield™ Lactose Monohydrate IP/BP/EP/USP-NF 325M**

\* Have more than 3 variants with customized particle size distribution

\*\* All the products are available in standard packs of 25 kg except 325M which is available in 20 Kg. packaged in brown paper bags.

## Moisture Uptake Study – Crystalline Lactose



## Application Research

### Sachet - How do you match equivalents? Justify??

- PSD
- Content Uniformity
- Minimum Deviation from Current Process / Method
- Equivalent / Better Flow
- Less Inter-particulate Interactions
- Comparable Price

## Description – Competitor M & Sheffield™ DC60

### Competitor M

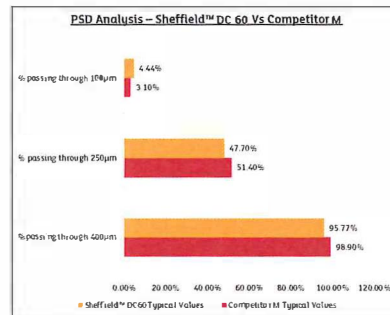
- Sieved alpha-lactose monohydrate.
- Little Agglomerates.
- Suitable for sachets & capsule filling
  - Excellent Flowability
  - Narrow PSD
  - 3 Years Shelf Life

### Sheffield™ DC60

- Sieved alpha-lactose monohydrate
- Directly Compressible
- Suitable for tablets, sachets & capsule filling
  - Excellent Flowability
  - Narrow PSD
  - 5 Years Shelf Life

## PSD Analysis – Competitor M & Sheffield™ DC60

Parameters	Competitor M	Sheffield™ DC60
Inspection Characteristics	Typical Values	Typical Values
% passing through 400µm	98.9%	95.77%
% passing through 250µm	51.4%	47.7%
% passing through 100µm	3.1%	4.44%



- Above data proves, Kerry's Sheffield™ DC60's PSD is ~5% away from Competitor M
- Higher chances of yielding same formulating mixture without any major changes in process

## Key Properties – Competitor M & Sheffield™ DC60

### Competitor M

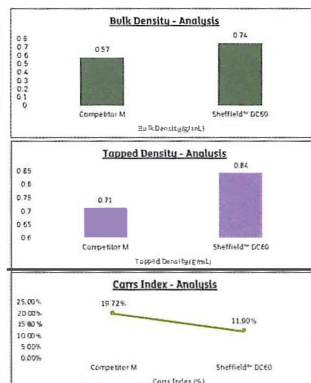
- Bulk Density – 0.57g/mL
- Tapped Density – 0.71g/mL
- Carrs Index – 19.72%

### Sheffield™ DC60

- Bulk Density – 0.738g/mL
- Tapped Density – 0.836g/mL
- Carrs Index – 11.9%

### Observations:

- Competitor M – Difference between tapped & bulk density (0.14g/mL)\*
- Sheffield™ DC60 – Difference between tapped & bulk density (0.10g/mL)\*
- Sheffield™ DC60 – Good Flow
- Competitor M – Fair Flow



\*In a free-flowing powder, the bulk and tapped densities will be higher than for poorly flowing materials. Therefore, the difference between bulk and tapped density will be observed.



### Comparable PSD

Exhibited Sheffield™ DC60 has comparable PSD with Competitor M.

### Densities

Exhibited Sheffield™ DC60 has better balance between tapped & bulk density.

Less inter-particulate interactions.

### Flow

Exhibited Sheffield™ DC60 has good flow characteristics.

Carrs Index– 11%

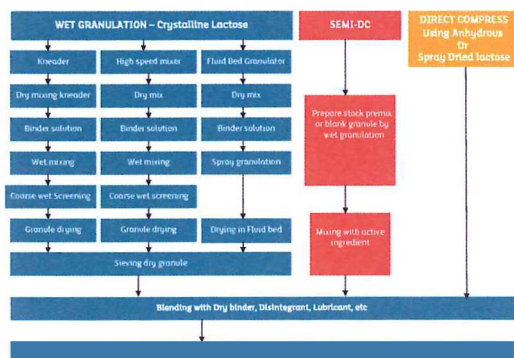


Please discuss below with our Account Manager:

1. Logistics benefits (air gear crossing 10-20%)
2. Shelf Life benefits (a stable 18m contributes in stability of dosage form)

### DC Lactose

### Typical Production Process for Tableting

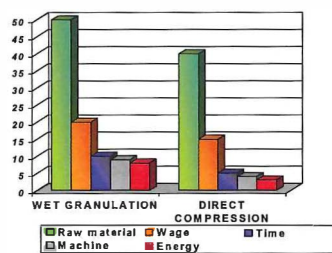


### Benefits of Direct Compression:

- Less costly than WG
- Less processing steps equals better consistency
- No water addition to affect moisture sensitive API's
- Less excipients – many DC excipients already dissolve fast so can eliminate super-disintegrants
- There is a lubricated excipient on the market which revolutionizes DC applications - LubriTose

### Direct Compression Advantages: lower unit costs

- Direct compression eliminates other excipients, simplifying processing steps and reducing intrinsic product costs



### Direct Compression Advantages: Improved formulation development

- Faster formulation development
- Substantial reduction in process validation
- Reduced time to clinical trials
- Reduced usage/waste of active ingredients
- Enhanced processing
  - Compactibility
  - Powder flow and blending
  - Strain rate
- Reduced number of excipients used
- Ability to increase drug loads

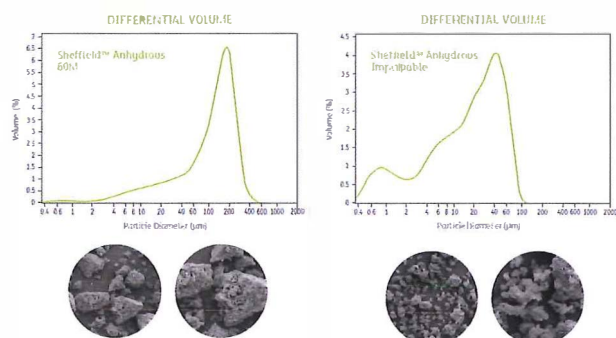


## Anhydrous Lactose

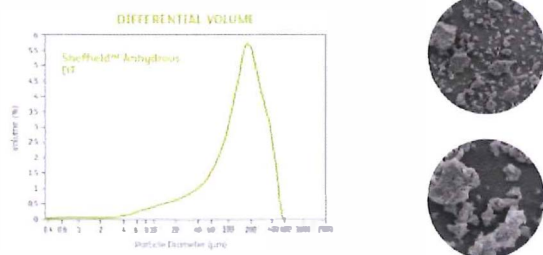
- Original patented manufacturing process:
  - High purity and consistency
  - Suitable for any high speed tableting process

Product	Application
Sheffield™ Brand Anhydrous Direct Tableting (DT)	Direct tableting (high flow not required)
Sheffield™ Brand Anhydrous 60M	 Granulations or Direct tableting (fine)
Sheffield™ Brand Anhydrous Impalpable	Direct tableting (high flow required)
Sheffield™ Brand Anhydrous DT High Velocity	

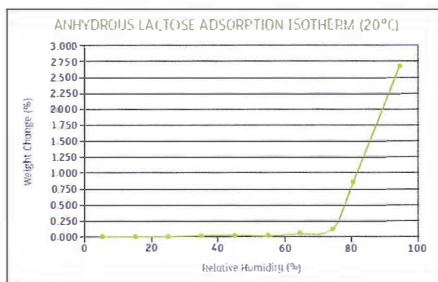
## Anhydrous Lactose: particle size



## Anhydrous Lactose DT: Particle Size



## Moisture Uptake Study

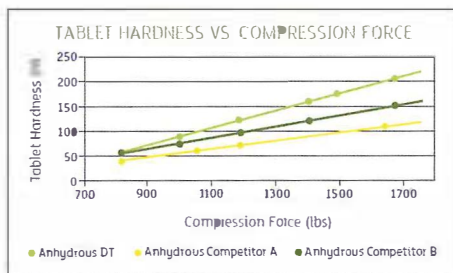


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More stable than monohydrate  
due to low moisture content.

## Anhydrous Lactose DT: Compressibility

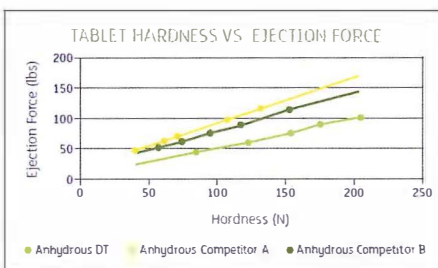


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$\alpha$ -Lactose for compression.

## Anhydrous Lactose DT: Hardness vs Ejection force

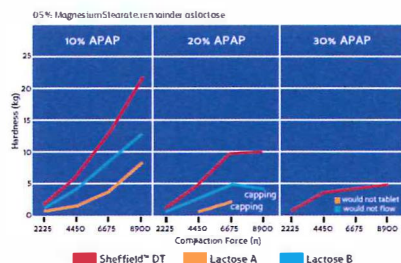


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## Direct Compression Improved Product Quality

- Reduced tablet/capsule weight variation
- Exceptional tablet hardness at low compression forces versus spray dried products
- Low compaction forces reduce equipment wear and maintenance
- Reduction in damaged tablets during coating

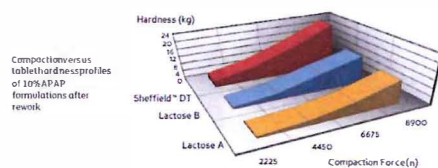


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## Direct Compression Improves Product Process

- Rework or reprocess with minimal change in final product categories



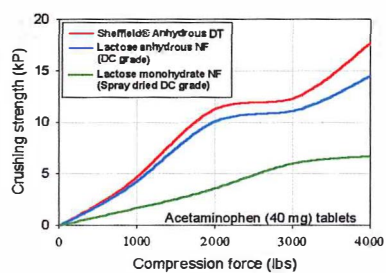
Properties of 10% APAP tablets before and after rework

Property	Hardness		Friability		Disolution	
	Initial	Rework	Initial	Rework	Initial	Rework
Sheffield DT	5.2	5.5	0.26	0.26	20	18
Lactose A	5.6	5.8	0.52	0.39	35	30
Lactose B	4.5	4.6	0.66	0.51	18	25

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## Best Suited for Direct Compression Applications

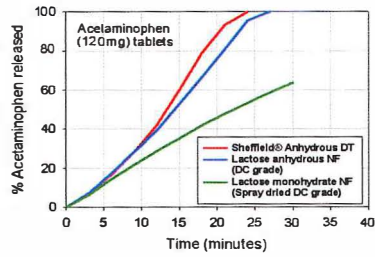


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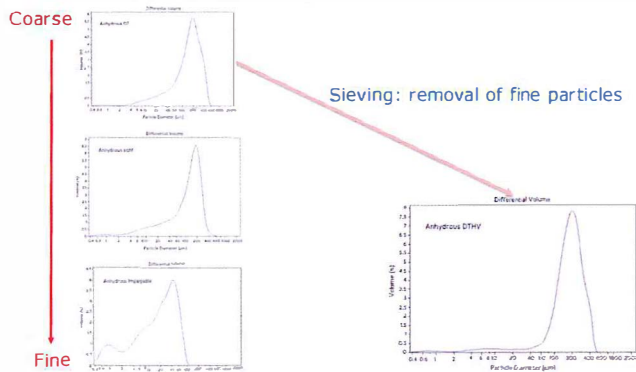


## Superior Binding and Improved Tablet Disintegration



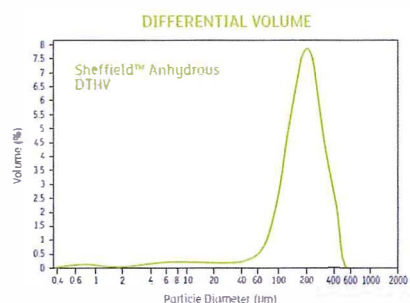
## Anhydrous DTHV

## Comparison of PSD of all Anhydrous Lactose



needs high compression force.

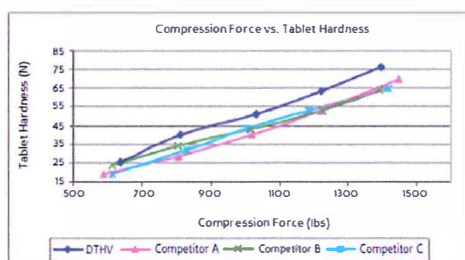
## Anhydrous Lactose DTHV: particle size



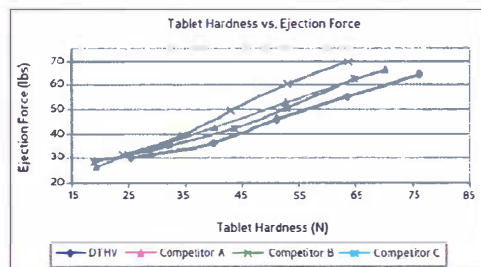
## Lactose Anhydrous DT High Velocity: advantages

- Low cost class of bulk solid excipients
- High speed, directly compressible grade
- Exceptional tablet hardness at low compression forces and faster speeds
- Improved powder flow in tablet press
- Less wear and tear to tooling
- Increase in tablet production
- High purity level minimizes potential for color development
- Physically and chemically stable, non-hygroscopic
- Low friability & excellent dissolution

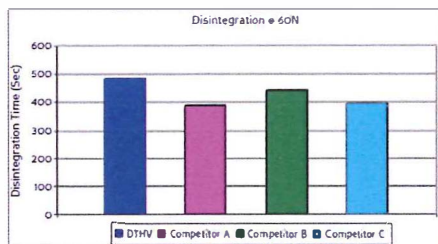
## Anhydrous Lactose DTHV: compression vs. tablet hardness



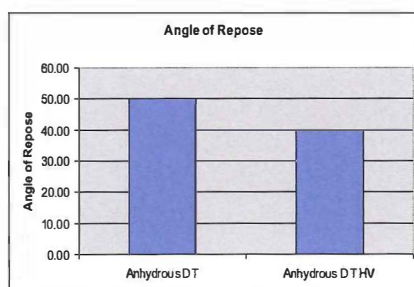
## Anhydrous Lactose DTHV: tablet hardness vs. ejection force



## Anhydrous Lactose DTHV: disintegration

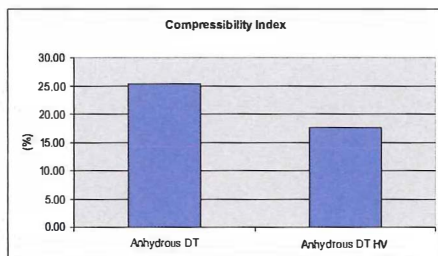


## Anhydrous Lactose DTHV: Angle Of Repose (AOR)



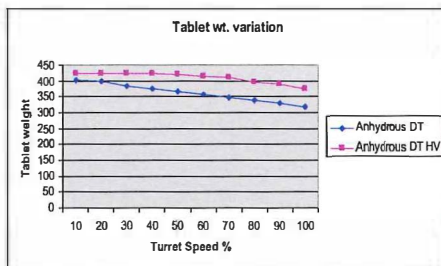
- Angle of Repose (AOR) values indicates there is 20% improvement in flow of Anhydrous DTHV against Anhydrous NF DT.

## Anhydrous Lactose DTHV: Compressibility Index



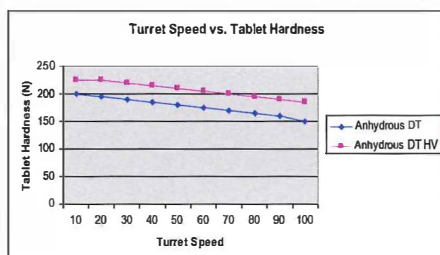
- Reduction in compressibility index of DTHV is expected due to \_\_\_\_\_ ????

## Anhydrous Lactose DTHV: Weight Variation



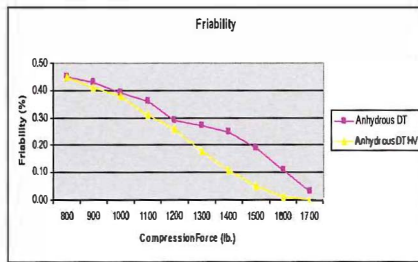
- DTHV has shown no change in weight of tablets upon increasing the turret speed up to 40%.
- However, DT shows weight variation upon increasing the turret speed to 20%.

## Anhydrous Lactose DTHV: Tablet Hardness



- DTHV has shown no change in tablet hardness upon increasing the turret speed up to 30%.
- However, DT shows drop in tablet hardness upon increasing the turret speed to 20%.

## Anhydrous Lactose DTHV: Friability



- In case of DTHV, the friability drops significantly upon increasing the compression force.
- In case of DT, due to relatively higher % of fine content, the flow is hindered, resulting insufficient filler during compression & yields relatively friable tablets.

## QUIZ TIME!! ANHYDROUS LACTOSE

3 KEY APPLICATIONS & 2 KEY BENEFITS OF KERRY'S ANHYDROUS LACTOSE??

### Applications

- Good Compressibility
- Protects the hygroscopic API from external moisture.
- Fast Disintegration → Release Profile.

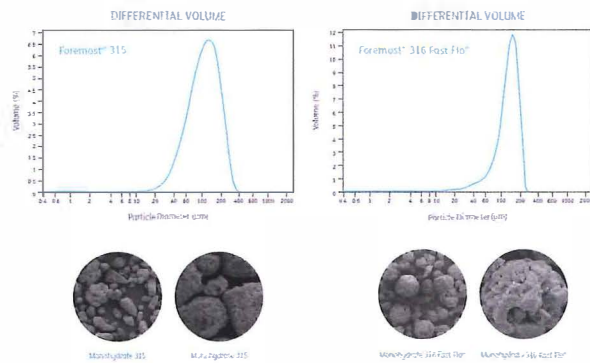
### Benefits

- Suitable for Rework & Reprocess
- High Velocity Compression Machine

DC Lactose



## Spray Dried Monohydrate: Particle Size

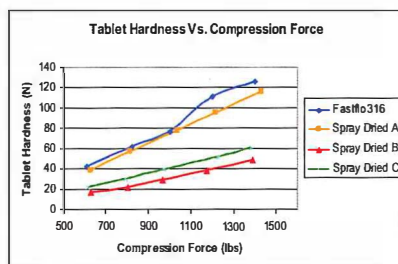


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the trick is to have  
circular particles.

## Foremost Fast Flo® 316: Compressibility

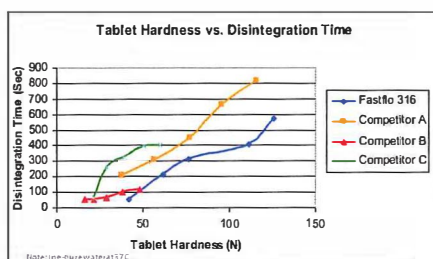


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very good compression.  
Soluble as monohydrate.  
Good flow.

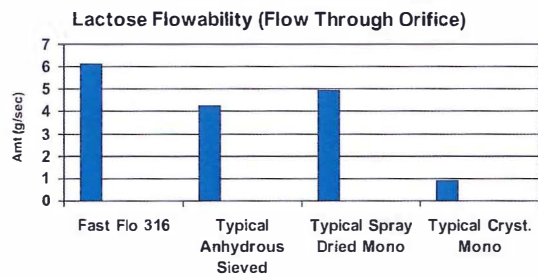
## Foremost Fast Flo® 316: Disintegration



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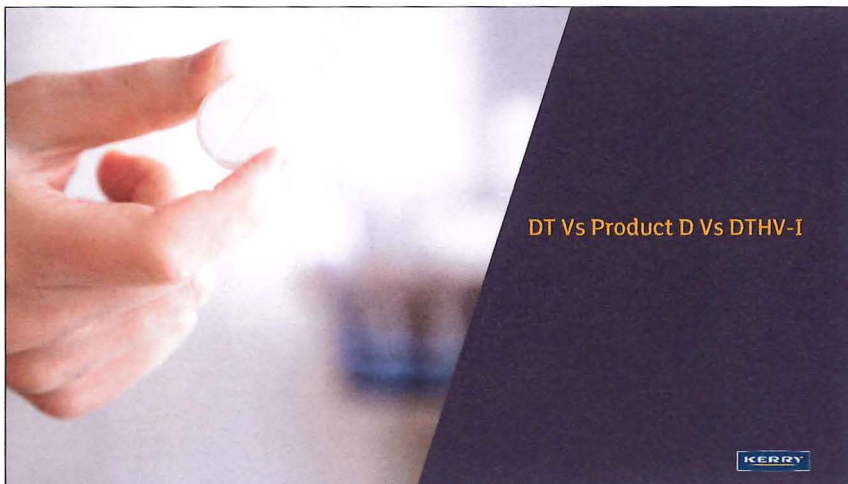
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## Foremost Fast Flo® 316: Flow Through Orifice



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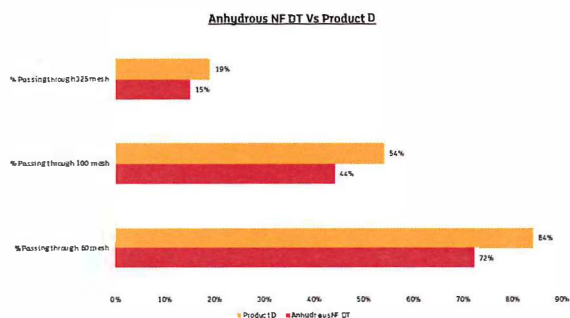
## Have you ever compared Kerry Vs Others??

- Who is Kerry's key competitor??
- Why customer use Anhydrous Lactose in formulation? Sort it based on priority please..
  - Very good flow
  - Moisture protection / Stability of finished dosage form
  - Direct compression
  - Solubility / Dissolution
  - Price

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## Anhydrous NF DT (5X59004) vs Product D



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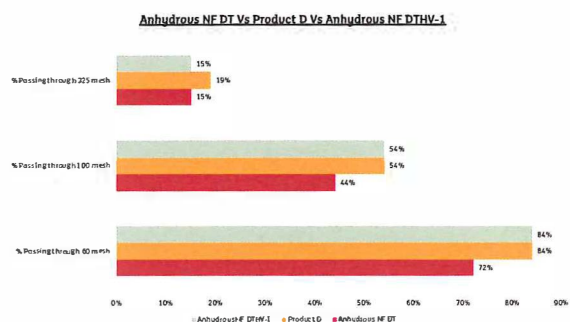
## Key Differences

- Product D has more finer particles over Kerry's 5X59004.
  - Better compression
  - Upon measuring flow – 20% Carrs' Index
- In addition, Product D's beta lactose is 80%; Kerry's beta lactose is 70%.
- With higher beta lactose, you may expect faster dissolution from Product D.
- However, the shelf life would be shorter as well.

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## On-Demand - Launched a Counter Anhydrous



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### Counter Product's Features

- Matches ~100% PSD of Product D
- Flow is compromised by 2% due to higher % fines
- Relatively better compression than NF DT
  - Higher % fines
  - Higher % alpha lactose
- Retained 4 years shelf life against 2 years of competitor D

### Comparison of SD Lactose

Foremost 316 Vs Competitor M

Foremost 316 Vs Competitor D

### How do you match equivalents? Justify??

- PSD
- Content Uniformity
- Minimum Deviation from Current Process / Method
- Equivalent / Better Flow
- Less Inter-particulate Interactions
- Comparable Price

### PSD Analysis of SD Lactose

Mesh Size	Competitor D (%)	FastFlow 335 (%)	Competitor M (%)
% passing through 22 µm (-200 mesh)	5%	5%	5%
% passing through 45 µm (-225 mesh)	13%	5%	5%
% passing through 75 µm (-200 mesh)	23%	21%	21%
% passing through 105 µm (-140 mesh)	44%	32%	56%
% passing through 200 µm (70 mesh)	89%	50%	87%
% passing through 250 µm (60 mesh)	99%	100%	97%

Legend: Competitor D (light grey), FastFlow 335 (orange), Competitor M (red)

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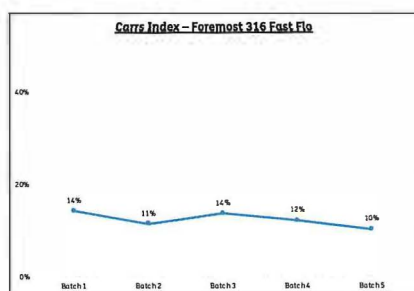
Carr's Index - Spray Dried Lactose

Product	Carr's Index (%)
CompetitorD	17%
CompetitorB	14%
Foremost 315	14%
Foremost 316	13%
CompetitorM	17%

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### Batch to Batch Consistency – Last 5 Years



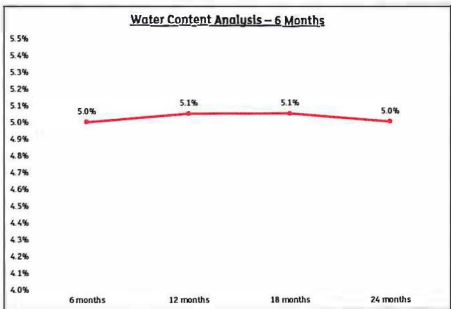
- Kerry, follows a robust, reproducible manufacturing process.
- Kerry ensures consistent delivery of spray dried lactose with enhanced flowability.
- All 5 batches of Foremost 316 represented in this graph were manufactured in last 5 years.
- Consistently delivering promises





Consistency of Foremost 316 – Water Content

6 Month Window - Analysis



- Foremost 316 particle morphology doesn't support moisture absorption.
- Consistent inherent water content across 2 years exhibits the product's stability in ambient conditions.
- No additional moisture absorption leads to multiple benefits;
  - Consistent Flowability.
  - No tablet weight variation.
  - No sticking of tablets

Comparable PSD

Exhibited Foremost 316 has comparable PSD with other SD Lactose.

Flow

Exhibited Foremost 316 has best flow among all SD Lactose

Carrs Index– 13%

Water Content

Exhibited Foremost 316 has consistent water content for a period of 2 Years.



Introducing  
**Reddi Flo® AG**  
Designed for Optimal Flow,  
Compression, & Stability



## Reddi Flo® AG

Designed for Optimal Flow, Compression, and Stability

Kerry's newest compressible lactose grade

Produced by a carefully controlled spray agglomeration process

Results in a high flowing, low amorphous compressible agglomerates

Complements our range of directly compressible lactose that includes spray dried and anhydrous

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## Reddi Flo® AG SEMs

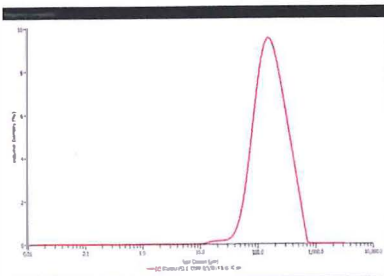
In the below images, it can be seen that there are agglomerated crystals, some individual crystals, and some spherical agglomerates



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## Agglomerated lactose – PSD and SEM



In the images, it can be seen that there are agglomerated crystals, individual crystals and some agglomerates more spherical

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## Lactose compressibility – the different grades

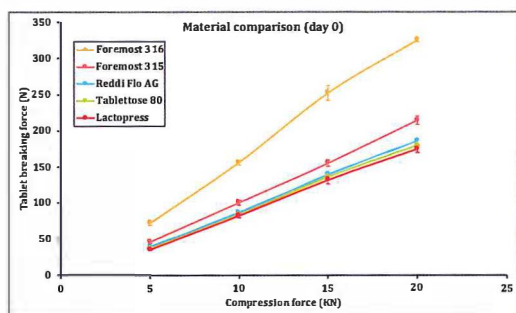


- **Spray dried lactose**
  - Amorphous content acts as a binder
  - High amorphous content (~6%)
  - Amorphous content reduces stability
- **Anhydrous lactose**
  - Compressible due to presence of beta lactose crystals
  - Brittle fracture mechanism of compression
- **Agglomerated lactose**
  - Agglomeration provides unique morphology
  - Low amorphous content (~2%)
  - Improved stability

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## Compressibility Compared to Marketed Grades



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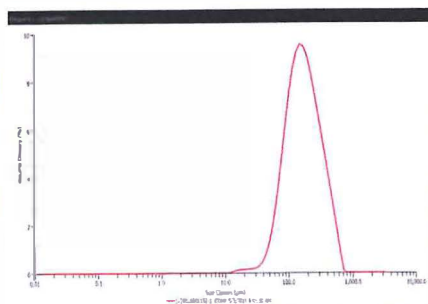
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## Particle Size

### Air Jet Sieve Specifications

Reddi Flo® AG	Spec	Typical
% < 63 µm	Max 20	5
% < 180 µm	40-75	60
% < 400 µm	Min 85	97
% < 630 µm	Min 97	100

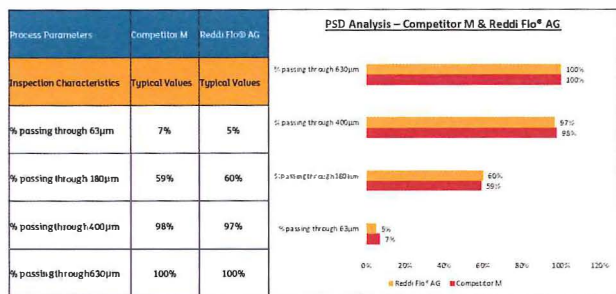
### Typical Laser Scan



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## Comparative PSD Analysis – Competitor M & Reddi Flo® AG



- Above data proves, Kerry's Reddi Flo® AG PSD is equivalent to Competitor M
- Higher chances of yielding same formulating mixture without any major changes in process

## Key Physical Properties – Competitor M & Reddi Flo® AG

Competitor M	Reddi Flo® AG
<ul style="list-style-type: none"> <li>• Bulk Density – 0.62g/mL</li> <li>• Tapped Density – 0.77g/mL</li> <li>• Carrs Index – 19.48%</li> </ul>	<ul style="list-style-type: none"> <li>• Bulk Density – 0.7g/mL</li> <li>• Tapped Density – 0.82g/mL</li> <li>• Carrs Index – 12% 14.6</li> </ul>

### Observations:

- Competitor M - Difference between tapped & bulk density (0.15g/mL)\*.
- Reddi Flo® AG – Difference between tapped & bulk density (0.12g/mL)\*.
- Reddi Flo® AG – Excellent Flow
- Competitor M – Good Flow

## Comparable PSD

Exhibited Reddi Flo® AG has comparable PSD with Competitor M.

## Densities

Exhibited Reddi Flo® AG has better balance between tapped & bulk density.

Less inter-particulate interactions.

## Flow

Exhibited Reddi Flo® AG has good flow characteristics.

Carrs Index – 12%



## Comparing DC Lactose - Flow

Product	Angle of Repose	Carr's Index	Flowability
Foremost Fast Flo® 316	13	10	Excellent
Reddi Flo® AG	15	12	Excellent
Sheffield™ Anhydrous DTHV	40	18	Good
Sheffield™ Anhydrous DT	50	25	Acceptable

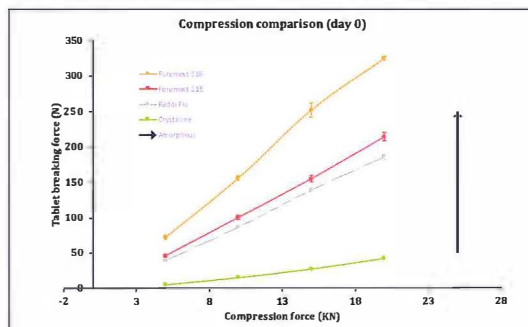


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## Comparing DC Lactose - Compressibility

Compressibility increases as amorphous content increases



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316 Best Compressability  
and Flow.

## Arbitrary Scale – DC Lactose



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## Conclusion – DC lactose comparison

		Foremost 315	Anhydrous DT	Anhydrous DTHV	Reddi Flo AG
Flow	★★★★★	★★★	★★	★★★★	★★★★★
Compressibility	★★★★★	★★	★★★★★	★★★★★	★★
Moisture Stability	★★	★★★	★★★★★	★★★★★	★★★★★

- If you have a moisture sensitive API use anhydrous lactose
- All lactose grades have sufficient flow for high speed tableting
- If you want very hard tablets or API is not very compressible use Anhydrous DTHV or Foremost 316
- If you want fast flow and very hard tablets use Foremost 316
- If you want fast flow and stability is an issue use Reddi Flo AG

## QUIZ TIME!!! Reddi Flo AG

1. LOD of Reddi Flo AG is 0.6% → True / False
2. Which DC Lactose of Kerry exhibits fastest flow? 316
3. Spray Dried Lactose (Foremost 316) has 6 % of amorphous content. Spray Agglomerated Lactose (Reddi Flo) has 1 % of amorphous content?

Agglomerated LOD less than  
Spray dried.



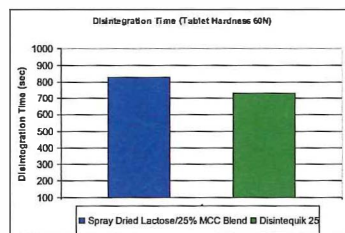
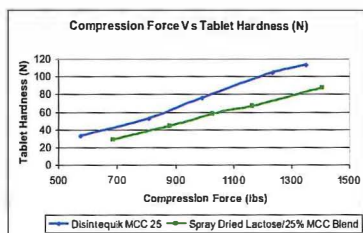
Disintequik™ MCC25

## Disinteqik™ MCC 25

- Co-processed lactose and co-binder excipients designed for direct compression where hard tablets and fast disintegration is desired
- Co-processed optimizes the desired performance characteristics of each ingredient
- Improves performance properties over simple blends of ingredients

Product	Co-Processed Ingredients	US/FDA DMF#
Disinteqik™ MCC25	Monohydrate Lactose NF/EP/JP (75%) Microcrystalline Cellulose NF/EP/JP (25%)	24492

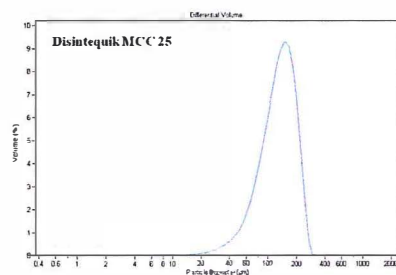
## Disinteqik™ MCC25 Increases Hardness and Faster Disintegration Over Physical Blend



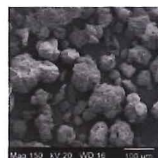
- Co-processing boosts performance

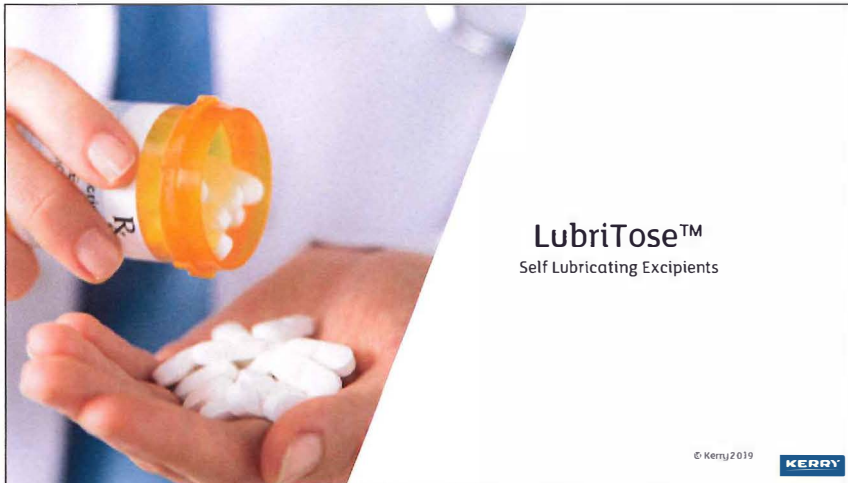
Co-processed 25 is almost  
100 times better disintegration.

## Particle size and appearance



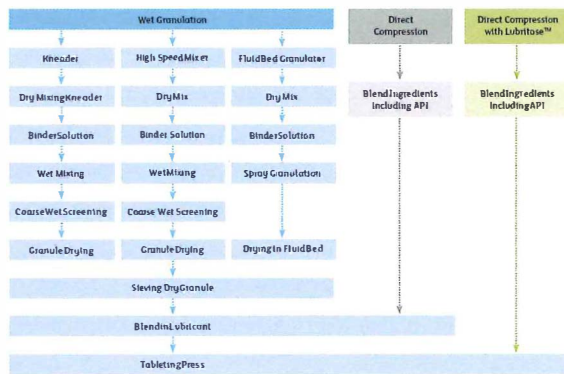
- Low dust
- Regular shape
- Granule allows water to penetrate, helping dissolution





\*No need for Lubricant.

## Simplifying the Tableting Process



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## LubriTose™ Key Benefits

- Integrated co-processed systems that combines a directly compressible excipient with a lubricant designed for direct compression operations
  - Reduces processing steps
  - Eliminate needs for external lubricant and time critical blending
  - Improves powder flow and tablet weight uniformity
  - No impact on compression properties or API dissolution
  - Available with lactose, MCC, or mannitol as 'base' excipient in customized ratios with GMS

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Note: There is not a monoglyceride monoglyceride/EP/JP

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GMS : Glycerol monostearate

## LubriTose™ - Product Line

Co-Processed Ingredients — typical levels	LubriTose Variants
Lactose NF/EP/JP (96%) Glyceryl Monostearate NF (4%)	LubriTose™ AN (Anhydrous) LubriTose™ SD (Spray Dried)
Mannitol NF/EP/JP (96%) Glyceryl Monostearate NF (4%)	LubriTose™ Mannitol
Microcrystalline Cellulose NF/EP/JP (98%) Glyceryl Monostearate NF (2%)	LubriTose™ MCC
Anhydrous Lactose NF DT USP, Ph. Eur., JP (50%) Microcrystalline Cellulose NF/EP/JP (48%) Glyceryl Monostearate NF (2%)	LubriTose™ PB

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LubriTose PB moisture sensitive.

Minimum 60% in formula.



**Disinteqik™ ODT**  
Co-Processed Orally Dissolving  
Tablet formulation

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## Disinteqik™ ODT Overview

- Co-processed excipient system designed for use in direct compression, orally disintegrating tablets
- Monograph compliant ingredients and DMF registration assure acceptance by all major global regulatory agencies
- All ingredients are listed in the FDA Inactive Ingredients Database, meaning that the ingredients are present in currently approved FDA drug products

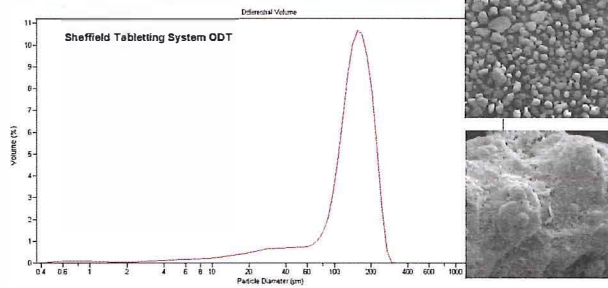
Product	Co-Processed Ingredients	US/FDA DMF
Disinteqik™ ODT	Lactose Monohydrate NF/EP/JP Spray Dried Mannitol NF/EP/JP Crospovidone NF/EP/JP Dextrose Monohydrate NF/EP/USP	Granted

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## Disintequik™ ODT particle size and appearance

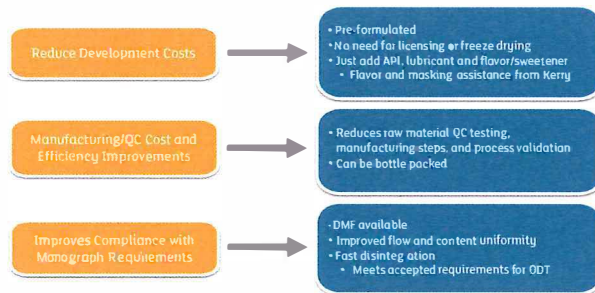
- High flowability due to particle shape
- Low dusting due to granulation
- Porous particles for fast disintegration



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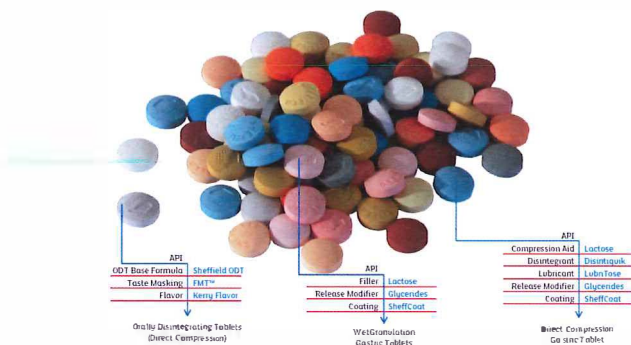
## Disintequik™ ODT adding value to your business



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## Integrated Product Portfolio



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Your feedback helps us in  
serving you better.  
Lets save trees and use  
this QR code to begin the  
survey!

Thank you

